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A comparative study of three treatment interventions for chronic patellar tendinopathy: a protocol for a randomized controlled trial

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1 A comparative study of three treatment interventions for chronic patellar tendinopathy:
2 a protocol for a randomized controlled trial

3 López-Royo MP^{a,b}, Gómez-Trullén EM^b, Ortiz-Lucas M^a, Galán-Díaz RM^a, Bataller-Cervero
4 AV^a, AL-boloushi Z, Hamam-Alcober Y^a, Herrero P^{a*}

5 AFFILIATIONS

6 **A.** iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov.
7 A23 km 299, 50830. Villanueva de Gállego, Zaragoza, Spain.

8 **B.** Universidad de Zaragoza. Facultad de Ciencias de la Salud. Dpto. de Fisiatría y
9 Enfermería. C/ Domingo Miral s/n, 50009 - Zaragoza, Spain.

11 *CORRESPONDENCE TO:

12 Dr. Pablo Herrero. iPhysio Research Group. Universidad San Jorge. Campus
13 Universitario, Autov A23, Km 299, 50830 Villanueva de Gállego, Zaragoza, Spain.
14 Tel.: (+34) 976 060 100 Fax: 976 077 581. Email: pherrero@usj.es

15 ADDITIONAL AUTHOR INFORMATION

16 Maria Pilar López Royo. Emails: mplopez@usj.es

17 Eva María Gómez Trullén. Email: evagomez@unizar.es

18 María Ortiz Lucas. Email: mortiz@usj.es

19 Rita María Galán Díaz. Email: rmgalan@usj.es

20 Ana Vanessa Bataller-Cervero. Email: avbataller@usj.es

21 Yasmina Hamam-Alcober. Email: yhamam@usj.es

22 Zaid AL-boloushi. Email: boloushi@gmail.com

1
2
3 **23 ABSTRACT**
4

5 **24 Introduction:** Chronic patellar tendinopathy is a degenerative disease of the patellar
6
7
8 **25** tendon, which affects athletes from a variety of sports, and is especially predominant in
9
10
11 **26** sports involving high-impact jumping. The aim of this study is to compare the
12
13 **27** effectiveness of needling therapies in order to determine the most effective treatment
14
15 **28** protocol of chronic patellar tendinopathy.

16
17 **29 Methods and analysis:** This study is a randomized controlled trial with blinded
18
19
20 **30** participants. Measurements will be carried out by a specially trained blind assessor. A
21
22 **31** sample of 57 patients with a medical diagnosis of patellar tendinopathy will participate
23
24 **32** in this study for a minimum of three months and will be divided into three treatment
25
26 **33** groups. Eligible participants will be randomly allocated to receive either: (a) treatment
27
28 **34** group with Percutaneous Needle Electrolysis, (b) treatment group with Dry Needle or (c)
29
30 **35** treatment group with placebo needling and all of the them realized eccentric exercise.
31
32
33 **36** Functionality and muscle strength parameters, pain, histological changes and patient
34
35 **37** perceived quality of life shall be evaluated by Visa-p, jumps, VAS, US images and SF-
36
37 **38** 36, respectively. Follow-up measurements will take place two and 12 weeks after the final
38
39 **39** treatment. The expected findings could be a breakthrough for the treatment of this injury
40
41
42 **40** as they would allow to define the most effective treatment protocol to deal with this
43
44 **41** disease and avoid the consequences that derive from it, reflecting all of this in a new
45
46 **42** relapse prevention.

47
48
49 **43 Ethics and dissemination:** This protocol has been approved by Ethics Committee of
50
51
52 **44** Aragon (N° PI15/0017). The trial will be conducted in accordance with the Declaration
53
54 **45** of Helsinki.

55
56 **46 Trial Registration Number:** NCT02498795.
57
58
59 **47**
60

48 **Strengths and limitations of this study**

49 - This randomised clinical trial will report the effects in functionality and pain of three
50 different treatments at short and long term.

51 - The double-blinded and placebo-control design improve the objectivity and help reduce
52 bias.

53 - The effects between two minimally invasive treatments in physical therapy will be
54 compared for the first time in patellar tendinopathy.

55

56 **INTRODUCTION**

57 Chronic patellar tendinopathy (CPT), also known as jumper's knee, is a degenerative
58 disease of the patellar tendon resulting in anterior knee pain associated with focal and
59 palpable tenderness at the inferior pole of the patella. This disorder has similar histologic
60 findings to other tendon disorders characterized by an increased thickness of the tendon
61 and changes in vascularity, and cellularity, with incompletely healed tendon micro-
62 ruptures and disturbed collagen distribution [1].

63 This disorder affects athletes from a variety of sports, and is especially predominant in
64 sports involving high-impact jumping. The overall prevalence of CPT in non-elite players
65 is 8.5%, although this figure increases in sports that place high demands on the patellar
66 ligament, increasing up to 14.2% in volleyball athletes. Among elite volleyball and
67 basketball players, a prevalence of 45% and 32%, respectively, has been reported. In
68 addition, jumper's knee is almost twice as common among male non-elite athletes when
69 compared with female athletes [2].

70 The diagnosis is typically based on the clinical history and symptomatic findings.

71 Currently, imaging techniques, such as color-Doppler ultrasound (CD-US) and gray scale
72 ultrasound (GS-US) may represent the best combinations to confirm clinically diagnosed

1
2
3 73 CPT. The GS-US has higher sensitivity than magnetic resonance imaging (MRI).
4
5 74 Therefore, ultrasound (US) techniques are more accurate than MRI for confirming
6
7 75 clinically diagnosed CPT [3].
8
9
10 76 Treatments used for CPT fall into two major groups. On the one hand, medical treatments
11
12 77 which include non-steroidal anti-inflammatory drugs (NSAIDs), platelet-rich plasma
13
14 78 injection [4], polidocanol [3] and autologous growth factors [5]. On the other hand, physical
15
16 79 therapies, including both conservative and invasive approaches (needling techniques).
17
18
19 80 Conservative therapies are generally accepted as the first line approach for managing
20
21 81 CPT, with eccentric exercise (EE) considered the gold standard [6, 7]. In 2012, EE was
22
23 82 shown to be effective in the treatment of tendinopathies at various locations of the body,
24
25 83 including CPT, and there was a greater likelihood of clinical improvement when
26
27 84 performed on a declined surface [6,8]. In recent years, further evidence now supports the
28
29 85 fact that exercise is more effective than other conventional treatments in tendinopathy,
30
31 86 such as iontophoresis, US, Cyriax treatment, etc [9].
32
33
34
35 87 Physical therapy approaches for CPT continue to evolve and a number of innovative
36
37 88 treatment options are now available, such as dry needling (DN) [10], electrotherapeutic
38
39 89 invasive modalities (e.g. electrolysis) [11-13] and extracorporeal shockwave (ECSW)
40
41 90 therapy [14]. Recently, research has focused on regenerative therapies with high
42
43 91 expectations of success because many of these techniques achieve a rapid regeneration of
44
45 92 the injured tendon. However, evidence-based regenerative therapies are limited and there
46
47 93 is no agreement to date regarding which of these is the most effective [15]. Dry needling
48
49 94 consists of the insertion of a needle (filiform and solid, non-beveled) with the aim of
50
51 95 provoking a local injury leading to an inflammatory response and the subsequent
52
53 96 regeneration of the injured area in approximately one week. A study performed by Abat
54
55 97 et al. reported that DN induced histological and mechanical changes in rat Achilles
56
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2
3 98 tendons at week one, with changes persisting at week four ^[16]. Percutaneous Needle
4
5 99 Electrolysis (PNE) is an ultrasound guided technique used by physiotherapists consisting
6
7
8 100 of causing localized lysis in the damaged and/or degenerated tissue by means of a
9
10 101 galvanic current transmitted through an acupuncture needle. This technique may affect
11
12 102 inflammatory mediators in damaged muscle tissue and influence the new vascularization
13
14 103 of the injured area in rats ^[16]. James et al.^[10] carried out a cohort study in humans
15
16 104 analyzing one group treated with DN and another treated with autologous blood
17
18 105 injections. In both cases, they found improvements with regard to the beginning of the
19
20 106 treatment, however failed to find differences between them, concluding that both
21
22 107 technologies were equally effective. In relation to PNE, a study ^[13] analyzed the treatment
23
24 108 effect of electrolysis applied once a week in a group of patients without any control or
25
26 109 comparative group, reporting that patients obtained statistically and clinically significant
27
28 110 improvements with regard to the baseline measurements. In another study ^[17] this
29
30 111 technology was compared with other conventional treatments (US and currents), showing
31
32 112 that PNE treatment was more effective than conventional treatment.

33
34
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36
37 113 From a biological point of view, it seems reasonable to ascertain that a patient will obtain
38
39 114 benefits thanks to the mechanical effects provided by the needle, and that patients may
40
41 115 benefit more if the electrolysis effect is added to the mechanical stimuli provided by the
42
43 116 needle.

44
45
46 117 Therefore, the aim of this study is to know whether invasive techniques has additional
47
48 118 effects for the treatment of CPT when compared with only EE, and if the application of
49
50 119 PNE provides any additional benefits aside from only performing DN, in the short and
51
52 120 long term.

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56 121

57 58 59 122 **METHODS AND ANALYSIS**

1
2
3 123 **Study design**
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5 124 The trials is designed as a randomized, controlled, participant, investigator and outcomes
6
7 125 assessor blinded, experimental study, whose purpose is to compare three protocols in
8
9 126 which different physiotherapy protocols are applied in three intervention groups with
10
11 127 CRT patients. Randomization will be performed as block randomization with a 1:1
12
13 128 allocation.
14
15

16
17 129 This protocol follows the standards of the Helsinki Convention of good clinical practices.
18
19 130 The Ethics Committee of Aragon (CEICA) has evaluated the project and has given its
20
21 131 favorable opinion and support, N° PI15/0017 (Appendix A).
22

23
24 132 The study has been carried out following the SPIRIT statement for clinical trial protocol
25
26 133 and a SPIRIT Checklist has been included (Appendix D).
27

28 134

29
30 135 **Studying sitting**
31

32 136 After reviewing the literature and observing the high incidence of this pathology in young
33
34 137 adults who perform sports and more specifically, jump sports, the search of patients has
35
36 138 been carry out in sports clubs of basketball, football, volleyball, CrossFit, handball,
37
38 139 running clubs and some gyms in the city. It is decided to carry out the study in X, where
39
40 140 the university is located as well as the laboratory that will be made use for assessments
41
42 141 and treatments.
43
44

45
46 142 The assessments will be conducted at the Motion Analysis laboratory of X, and the
47
48 143 treatment will be performed at two different sites depending on the availability both of
49
50 144 spaces and of schedules, albeit the same material shall always be used.
51

52 145

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54
55 146 **Participants**
56

57 147 *Inclusion criteria*
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1
2
3 148 Participants eligible for inclusion in this study must meet the following criteria: 1. History
4
5 149 of CPT and pain at the level of the patellar tendon for over three months; 2. Aged between
6
7 150 18 and 45 years; 3. Palpation tenderness of the patellar tendon; 4. A score below 80 on
8
9 151 the VISA-P questionnaire.

152 *Exclusion criteria*

153 Exclusion criteria for the study are: 1. Knee surgery within the previous six months; 2.
154 Chronic joint diseases; 3. Injection with corticosteroids within the previous three months;
155 4. Contraindications for needling; 5. Use of drugs 48 hours previously (e.g. NSAIDs).

156

157 **Methodology**

158 In the first session, all participants will be instructed how to perform a daily home
159 program of EE. This will consist of performing three sets of 15 single leg squat repetitions
160 on a decline board every day, according to Alfredson's protocol [18].

161 For the interventions, the participants will be placed in a supine position with a pillow
162 under the knee (approximately 20° of knee flexion). The area will be cleansed with an
163 antiseptic solution (70% Propan-2-ol, Skin-des). An ultrasound probe cover will be used
164 during the intervention for infectious control. To determine the relevant treatment area,
165 two factors will be considered: 1) Palpation of the areas exhibiting higher sensitivity and
166 that reproduce the patient's symptoms; 2) Tendon areas showing degenerative changes
167 assessed under ultrasound. Each group will receive a total of four sessions distributed
168 throughout eight weeks of treatment, once every two weeks.

169 *G-DN and G-PNE*

170 Specific DN needles will be used during needling treatments, (Agu-punt, Spain).
171 Considering the thickness of the tendon and the approach, we shall use needles measuring
172 0.25 x 25 mm. The procedure will be guided by US to ensure the specificity of application

1
2
3 173 on the injured area and to guarantee that the procedure is safe for the patient. The DN
4
5 174 needle shall reach the relevant treatment area (areas with degenerative CPT changes).
6
7
8 175 Each session will consist of three needle insertions lasting three seconds each. In G-PNE
9
10 176 applications, an intensity of 3 mA galvanic current will be used during the three seconds
11
12 177 that the procedure lasts. The dose of 3 mA has demonstrated to be effective in the
13
14 178 treatment of tendinopathy injuries in animal models ^[12].

16
17 179 *GC*

18
19 180 A sham needle will be placed upon the treatment zone, simulating the same procedure as
20
21 181 the rest of participants enrolled in the other groups. The needle will be placed in a specific
22
23 182 holder and will be manipulated during the intervention to simulate a real treatment. This
24
25 183 holder will have a cover over the bottom part of the same in order to avoid the needle
26
27 184 contacting the skin.

28
29
30
31 185

32 33 186 **Outcomes**

34 35 187 *Baseline data*

36
37 188 Baseline data will include gender, age, height, weight, body-mass index, affected side,
38
39 189 level, sports and frequency of physical activity, duration of symptoms, medication and
40
41 190 infiltrations. A blinded observer will assess all participants at baseline, 10 weeks and 22
42
43 191 weeks after baseline.

44 45 192 *Primary outcome measure*

46
47 193 Participants will complete the VISA-P questionnaire at baseline. The VISA-P
48
49 194 questionnaire is designed to measure the severity of CPT. VISA-P score is the primary
50
51 195 outcome variable. This scale consists of eight questions, the first six questions of which
52
53 196 employ an analogical visual scale in order to assign a score of 0 to 10, where 10 represents
54
55 197 the optimum state, for the purpose of quantifying pain and function in different activities,
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3 198 whereas the last two questions assess the level of functionality and ability to perform
4
5 199 physical activity.

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7
8 200 *Secondary outcome measure*

9
10 201 At the first evaluation, participants will complete the Visual Analogical Scale (VAS),
11
12 202 considering the level of pain they feel while practicing their sport's activity. Participants
13
14 203 will be explained that a score of 0 indicates the absence of pain whereas a score of 10
15
16 204 represents the maximum tolerable pain. They will also complete a questionnaire to assess
17
18 205 their quality of life (SF-36) [19].

19
20
21 206 In order to assess tendon structure, a US evaluation using ultrasound equipment (Logic
22
23 207 S7 Expert, General Electric Healthcare) and a linear probe (MLG-15 5–10 MHz) will be
24
25 208 used. The ultrasonographic assessment protocol will be carried out according to the
26
27 209 Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European
28
29 210 Society of Musculoskeletal Radiology [20]. The ultrasonographic assessment will consist
30
31 211 of a longitudinal sequence from the tendon origin to the insertion and transverse sections
32
33 212 on the pole of the patella, the tendon body and its insertion on the tibial tuberosity, with
34
35 213 the subject in supine position, with 20° knee flexion, and a pillow under the knee. The
36
37 214 presence of degenerative signs compatible with the medical diagnosis of CPT (thickness
38
39 215 of the tendon, hypoechoic areas, irregularities affecting the cortical bone, calcifications)
40
41 216 that could be relevant for the selection of the target area will also be assessed. In addition,
42
43 217 CD-US assessment will be carried out to detect the presence of hypervascularization, with
44
45 218 the subject in supine position and with the knee relaxed in full extension, in order to obtain
46
47 219 further information to specifically define the target area.

48
49 220 Upon completion of the evaluation, a jump test will be carried out, measured with a force
50
51 221 platform (FP4060-10-2000, Bertec Corporation). In this evaluation, subjects will perform
52
53 222 three different jumps on the platform to analyze the maximum height of the jump, the
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3 223 eccentric power and the maximum concentric force performed. The protocol followed is
4
5 224 described in the Table A.
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9

225

226 **Participant timeline**

11
12 227 The study design will be a double-blind randomized controlled trial. The flow chart of
13
14 228 the trial is shown in Figure A.
15
16

229

230 **Sample size**

21
22 231 Regarding the sample size, a calculation of statistical power was made prior to the study.
23
24 232 Accepting an alpha risk of 0.05 and a beta risk in a bilateral contrast, 17 subjects are
25
26 233 needed in every treatment group to detect a difference equal or superior to 15 points on
27
28 234 the Visa-P scale ^[21], and assuming a standard deviation of 13.2 ^[22]. The estimated rate of
29
30 235 loss to follow-up is 20%.

32
33 236 Recruitment of subjects for the trial will take place between October 2018 and March
34
35 237 2020 and will be carried out by means of informative campaigns targeted at different
36
37 238 Sports Clubs and Federations by means of e-mail and advertisements in the different
38
39 239 University mass media.

41
42 240 The interested subjects will receive an e-mail explaining the inclusion and exclusion
43
44 241 criteria, as well as the purpose of the study. If they meet the defined criteria, they will be
45
46 242 invited to send us their medical diagnosis.
47
48

243

244 **Recruitment**

51
52
53 245 Participants will be recruited in sports clubs by the physiotherapist or the coach. There
54
55
56 246 have been conversations with various traumatologists, so that when they make a diagnosis
57
58
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1
2
3 247 in their examination room of this pathology they can refer us to the patients and begin to
4
5 248 be part of the study.
6
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8 249

9
10 250 **Allocation**

11
12 251 Participants will be randomly assigned to either GC or G-DN or G-PNE with a 1:1:1
13
14 252 allocation through opaque envelope.

15
16 253 Sealed opaque randomization envelopes with a study-specific participant number will be
17
18 254 supplied by an external statistician. A colleague not involved in the research study will
19
20 255 take the sealed opaque numbered envelopes in order, by number, and deliver the correct
21
22 256 envelope to the treating physical therapist. The envelope will contain a piece of paper,
23
24 257 which will be labelled with the same participant specific number, plus the group
25
26 258 assignment (G-PNE, G-DN or GC).

27
28 259 Participants who fulfill the inclusion criteria will receive the standardized oral and written
29
30 260 information, and, once they grant their consent to take part in the trial, they will be
31
32 261 randomized into either a combined intervention with electrolysis along with EE (G-PNE),
33
34 262 a DN intervention combined with EE (G-DN) or sham needling with EE (GC).
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42 264 **Blinding**

43
44 265 Assessments regarding clinical recovery will be conducted by an assessor blind to
45
46 266 treatment allocation. Due to the nature of the intervention, participants can be blinded to
47
48 267 allocation. To the other hand, the physiotherapist that do the intervention cannot be
49
50 268 blinded, but are strongly inculcated not to disclose the allocation status of the participant
51
52 269 at the follow up assessments. An employee outside the research team will feed data into
53
54 270 the computer in separate datasheets so that the researchers can analyse data without
55
56 271 having access to information about the allocation.
57
58
59
60

272

273 Data collection methods

274 For the data collection of the participants, an oral questionnaire is carried out in which
275 questions are asked to collect baseline data and about the pathology. Appendix B.
276 Different questionnaires and assessment scales (VISA-p, VAS, SF-36) in Spanish
277 version will be given to the participant when they go to the evaluation in paper and all
278 the time necessary to complete them will be left. Appendix C.

279

280 Data management and statistical analysis

281 In this study, all data will be entered electronically in the assessment room.
282 Originals scales and questionnaires will be entered and kept on file at the participating
283 site locked.
284 Participant files are to be stored in numerical order and stored in a secure and accessible
285 place and manner. Participant files will be maintained in storage for a period of 2 years
286 after completion of the study.
287 The statistical analysis will be carried out by an intention-to-treat analysis. Variables will
288 be described in number (percentage) and average (standard deviation) or median
289 (interquartile range) attending to their distribution. Quantitative variables will be
290 analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine
291 correct statistical tests according to these results.
292 Outcomes will be analyzed using mixed linear and logistic regression models considering
293 participants as a random effect and group of treatment as fixed factors. Baseline
294 characteristics will be introduced in the model as covariance. Numbers needed to treat
295 index will also be calculated. The primary aim of the analysis will be to calculate the
296 difference obtained in the Visa-P score after the intervention (final measurement - initial

1
2
3 297 measurement). Finally, the magnitude of the effect of the result shall be calculated and
4
5 298 therefore its clinical importance, by means of the following formula:
6

7
8 299
$$r = \sqrt{\frac{F(1,dfR)}{F(1,dfR) + dfR}}$$

9

10 300 The significance level set for all the analysis will be $p \leq 0.05$.
11
12

13 301

14 302 **ETHICS AND DISEMINATION**

15
16
17 303 The study design, procedures and informed consent procedure were approved and
18
19 304 consequently the study will be carried out in compliance with the Helsinki Declaration of
20
21 305 Human Rights. All participants will have to provide written Spanish informed consent.
22
23

24 306 Appendix A.
25

26
27 307 The trial's results will be published in peer-reviewed international journals or otherwise
28
29 308 made publicly available and will be presented at national and international conferences
30
31 309 and symposiums irrespective of the outcomes.
32

33
34 310 Any modifications to the protocol, which may impact on the conduct of the study,
35
36 311 potential benefit of the patient or may affect patient safety, including changes of study
37
38 312 objectives, study design, patient population, sample sizes, study procedures, or significant
39
40 313 administrative aspects will require a formal amendment to the protocol. Such amendment
41
42 314 will be approved by the Ethics Committee prior to implementation and notified to the
43
44 315 health authorities in accordance with local regulations.
45
46

47 316 All study-related information will be stored securely at the study site. All participant
48
49 317 information will be stored in locked file cabinets in areas with limited access. All records
50
51 318 that contain names or other personal identifiers, such as locator forms and informed
52
53 319 consent forms, will be stored identified by code number. All local databases will be
54
55 320 secured with password-protected access systems.
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3 321 **Availability of data and material:** The datasets used and/or analysed during the current
4
5 322 study are available from the corresponding author on reasonable request.
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7
8 323

9
10 324 **DISCUSSION**

11
12 325 The study expects to investigate the effects of physiotherapy punction techniques on pain,
13
14 326 functionality and quality of life in CPT.

15
16
17 327 CPT is a common cause of knee pain in which there is a degenerative disease of the
18
19 328 patellar tendon. Among the causes of CPT, extrinsic factors (eg, patellar tendon loading
20
21 329 with exercise) and intrinsic factors (eg, malalignment, high patella, imbalances) have
22
23
24 330 been proposed.^[23] Traditionally the focus has been on strengthening through EE of the
25
26 331 quadriceps and many reviews have shown that the effect of the treatment could be
27
28 332 estimated to give the patients a 50-70% change of improvement on pain and
29
30
31 333 functionality.^[6,24,25]

32
33 334 With regard with punction treatment, previous studies have shown a great improvement
34
35 335 in CPT using PNE in combination with EE and all patients of these studies report an
36
37 336 improvement after at least one month of treatment.^[11-13,16,17] This time is less than the
38
39
40 337 minimum three months needed to improve symptoms by applying other conventional
41
42 338 techniques (pharmacological and biological treatments, cold/heat techniques, shock
43
44 339 waves, etc.) Additionally, in a long-term study, in 2013, it could demonstrated that
45
46 340 improve symptoms quickly and steadily for at least 10 years ^[16]. This fact demonstrates
47
48 341 that this technique ensures that patients remain pain-free for a long period. Furthermore,
49
50 342 only 5 articles^[11-13,16,17] addressed the application of PNE for the recovery of CPT have
51
52
53 343 been found, but none of the articles studied were RCTs, which entail limited evidence of
54
55
56 344 the effectiveness of this technique.
57
58
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1
2
3 345 On the other hand, there are no standardized protocols for the application of PNE, which
4
5 346 explains the great variability in the number of sessions and application time according to
6
7 347 the literature. Therefore, this study aims to facilitate clinical practice and combine criteria
8
9 348 of methodology to use this technique with a promising future.

10
11
12 349 Regarding DN, the literature shows many similarities with the PNE, since there is only
13
14 350 one RCT that compares the improvement of functionality with patients who have received
15
16 351 PRP. In this study, it was reflected that at short term PRP had better results at pain and
17
18 352 functionality, however, DN was more effective than PRP after 6 months.^[26]

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20
21 353 In these two puncture techniques US is usually used to be able to observe in the first
22
23 354 instance how the tendon is presented, and later to be able to observe the needle and be
24
25 355 much more specific in the treatment. However, the US has disadvantages include its
26
27 356 operator dependence and the limited ability to rule out intra-articular disease with this
28
29 357 modality. The sensitivity and specificity of ultrasonography for patellar tendinopathy are
30
31 358 58% and 94%, respectively.^[27]

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35 359 There are several highlights to this study. First, we are going to evaluate two techniques
36
37 360 that do not have strong evidence yet, contributing in this way with new knowledge in the
38
39 361 field of the recovery of musculoskeletal injuries. Second, the role of invasive techniques
40
41 362 will be determinate by comparing the effects between these techniques and a control
42
43 363 group, being able to obtain reliable data since patients, like the assessor will be blinded.
44
45 364 Third, a sub-analysis with US will be performed to investigate changes in presence of
46
47 365 calcifications, cortical irregularities, neovascularization, thickness, eco-intensity, eco-
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49 366 variation and eco-texture of the patellar tendon.

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53 367 These findings could be a breakthrough for the treatment of this injury as they would
54
55 368 allow to define the most effective treatment protocol to deal with this disease and avoid
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3 369 the consequences that derive from it, reflecting all of this in a new relapse prevention and
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5 370 the potential impact on the musculoskeletal system.
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41 460 **AUTHOR'S CONTRIBUTIONS**

42
43
44 461 MPL, EMG and PH conceived of the idea, and developed the intervention. MPL and PH
45
46 462 wrote the article. MPL, MO, RMG, AVB, ZA, YH and PH developed the design of the
47
48 463 trial. MO were involved in development of the statistical analysis of the trial and
49
50 464 contributed to the content of the article. AVB contributed to the design and writing of the
51
52 465 jump test protocol. All authors have read and approved the final manuscript.
53
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56 466

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2
3 468 This research received no specific grant from any funding agency in the public,
4
5 469 commercial or not-for-profit sectors.
6
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8 470

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10 471 **COMPETING INTEREST STATEMENT**
11

12 472 The authors declare that they have no competing interests.
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17 474 **WORD COUNT:** 3431 words.
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493 **TABLES**

494 Table A. Jump test protocol.

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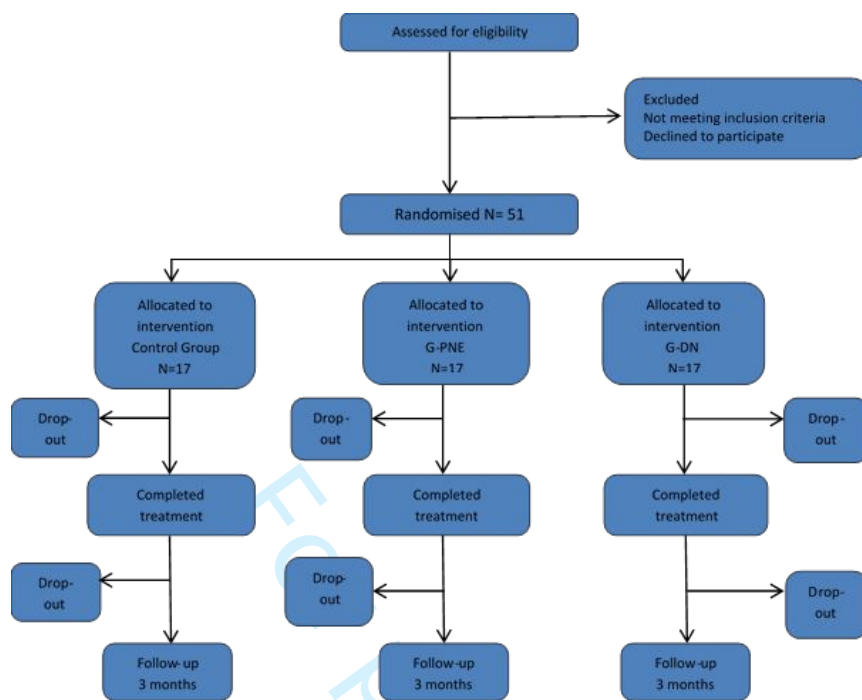
509 **FIGURES**

510 Figure A. Flow diagram. Randomized controlled trial design.

JUMP TEST PROTOCOL	
5-minute warm-up consisting of steady jogging on a treadmill	
Dynamic Stretches lasting 5 minutes, as instructed by the physical therapist	Psoas Quadriceps Gluteus maximus Gastrocnemius Hamstring muscles
Three jump tests are performed - 3 jumps off the ground for 3 times for the patient to become familiar with the tests - The subject is placed on the platform and asked to perform each test 3 times, with 60 seconds rest between the different tests	Abalakov test Countermovement jump test Squat jump
The highest jump is selected for the study	

509

510



511

512 G-PNE: Percutaneous Needle Electrolysis Group. G-DN: Dry Needle Group.

513

514 Figure B. Schedule of enrolment, interventions, and assessments.

	Enrolment	Allocation	Close-out			
TIMEPOINT**	-t ₁	0	t ₁	t ₂	t ₃	t ₄
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Control group			↔			
G-PNE			↔			
G-DN			↔			
ASSESSMENTS:						
Baseline demographic information	X					

<i>VISA-P</i>	X		X		X	X
<i>VAS</i>			X		X	X
<i>SF-36</i>			X		X	X
<i>Tendon structure US</i>			X		X	X
<i>Jump test</i>			X		X	X

515

516 Schedule for enrolment and intervention per cluster. -t1: baseline; t1-t2: intervention period;

517 t2: 8 weeks after baseline; t3: 10 weeks after baseline; t4: 3 month after baseline. G-PNE:

518 Percutaneous Needle Electrolysis Group; G-DN: Dry Needle Group; US: ultrasound.

519

520 **Appendix A. Informed Consent.**521 **DOCUMENTO DE INFORMACIÓN AL PACIENTE**

522

523 **Fecha:**524 **Título del proyecto: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN PARA**
525 **EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”**526 **Investigador principal:**527 Doña: M^a Pilar López Royo

528

529 Este estudio se basa en el estudio comparativo de tres tratamientos que utilizan distintas
530 técnicas de fisioterapia invasiva junto con un programa de ejercicio excéntrico para el
531 tratamiento de la tendinopatía rotuliana. Por medio del tratamiento se produce una
532 disminución del dolor asociado a esta patología y un aumento de la fuerza de la pierna,
533 lo que a su vez hace que mejore la funcionalidad en las actividades de la vida diaria y
534 mejore la calidad de vida.

535

536 **PROCESO DE SELECCIÓN DE PACIENTES**537 **Criterios de inclusión:**

538 - Edad comprendida entre 18 y 40 años.

- 1
2
3 539 - Practicar cualquier deporte de forma habitual.
4
5 540 - Pacientes con diagnóstico médico de tendinopatía rotuliana crónica con un
6 541 mínimo de 3 meses de evolución y con sintomatología.
7
8 542 - Dolor a la palpación del tendón en el polo inferior de la rótula y durante el
9 543 entrenamiento o competición.
10
11 544 - Puntuación del cuestionario VISA-P menor de 80 (el resultado obtenido de
12 545 rellenar el cuestionario tiene que ser menor de 80 puntos de los 100 posibles
13 546 para poder participar en el estudio).
14
15
16 547

17
18 548 Criterios de exclusión:

- 19
20
21 549 - Paciente operado de la rodilla afectada en los últimos 6 meses.
22 550 - Infiltraciones en la rodilla afectada en los últimos 3 meses.
23
24 551 - Paciente que ha recibido tratamiento farmacológico o fisioterápico en las últimas
25 552 48 horas o durante el estudio.
26
27 553 - Patología con menos de 3 meses de evolución.
28 554 - Presentar tendinopatía rotuliana bilateral.
29
30 555 - Puntuación del cuestionario VISA-p mayor o igual de 80 (el resultado obtenido
31 556 de rellenar el cuestionario no puede ser igual o superar los 80 puntos de los 100
32 557 posibles, sino no podrá participar en el estudio).
33
34 558 - Imposibilidad para aplicar alguna de las técnicas de tratamiento o valoración por
35 559 contraindicación absoluta o relativa.
36
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42 562 **PROCEDIMIENTO**

43
44
45 563 El tratamiento consiste en realizar un protocolo de ejercicios excéntricos de cuádriceps
46 564 que realizará en casa de forma diaria, y que serán revisados con el fisioterapeuta para
47 565 valorar su correcta realización. Se complementará el tratamiento con la aplicación de
48 566 una técnica de punción según el protocolo de tratamiento propuesto de forma totalmente
49 567 **aleatorizada** y según los criterios diagnósticos específicos de la misma, siguiendo las
50 568 indicaciones, criterios de aplicación y criterios diagnósticos.

51
52
53
54
55 569 Son técnicas de punción cuyo objetivo es producir una respuesta inflamatoria aguda que
56 570 active los mecanismos fisiológicos de regeneración del tejido y mejorar el dolor y la
57 571 funcionalidad en la articulación de la rodilla, se realiza con agujas de punción seca,

1
2
3 572 similares a las agujas de acupuntura y sin infiltrar ningún tipo de sustancia dentro del
4 573 organismo.

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6
7 574

8
9 575 Los registros serán realizados en el Espacio de Valoración Funcional de la Universidad
10 576 San Jorge, en la Facultad de Ciencias de la Salud, Edificio III. Se pondrá a su disposición
11 577 la posibilidad de utilizar el autobús que utiliza el personal y alumnado de la universidad
12 578 (en el horario que éste esté disponible). Las fechas y horarios serán convenidas con
13 579 cada participante en función de su disponibilidad y la de los investigadores, buscando
14 580 la conformidad de todos. La duración aproximada del estudio para cada paciente será
15 581 de 30 minutos, aunque este horario podrá variar en función de los acontecimientos.

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23 583 Será recibido por los miembros del equipo de investigación y una vez allí, se le realizará
24 584 un primer análisis fisioterápico, rellenará una encuesta, una escala analógica visual
25 585 (EVA) del dolor y el cuestionario Visa-p en el que se valorará la funcionalidad de la
26 586 rodilla.

27
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29
30
31 587 Tras éste primer registro se le colocará un marcador pasivo en el pantalón. Se le pedirá
32 588 que realice el siguiente protocolo:

- 33
34
35 - Calentamiento de 5 minutos en cinta a ritmo constante.
36 - Estiramientos dinámicos de psoas, cuádriceps, glúteo, gastrocnemios, isquiotibiales
37 durante 5 minutos instruidos por el fisioterapeuta.
38 - Realización de los 3 saltos fuera de la plataforma durante 3 veces para que se
39 familiarice con los tests.
40 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test
41 de salto con contramovimiento (CMJ) y el squatjump (SJ).

42
43 Se colocará en la plataforma y realizará 3 saltos de cada uno de los test con una
44 separación entre ellos de 60 segundos.

45
46 Se valora el tendón por ecografía, y se recogen datos por medio de personal adiestrado
47 y se envía a personal especialista en radiodiagnóstico.

48
49 589 Tras los registros de los saltos se dará por finalizada la valoración.

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56
57 591 Tras la 1ª valoración, se realizará una división en tres grupos de los pacientes de forma
58 592 aleatorizada.

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3 593 Se le realizará el protocolo de tratamiento de fisioterapia invasiva que le haya
4 correspondido. Realizará una sesión del tratamiento cada 14 días, y se realizará la 2º
5 594 valoración 1 semana más tarde de la 4º sesión de punción para valorar los cambios que
6 595 se hayan producido tras el tratamiento, repitiéndose de nuevo el proceso de recogida
7 596 de datos realizado al inicio del estudio. Se realizará un seguimiento a los tres meses de
8 597 la valoración post-tratamiento para valorar la eficacia de la técnica a largo plazo del
9 598 tratamiento.
10 599

11 600 El procedimiento se realizará guiado ecográficamente para asegurar la especificidad de
12 601 aplicación sobre la zona relevante de tratamiento y garantizar la seguridad de la técnica.
13 602 Se hace posterior a esta intervención una serie de ejercicios excéntricos de cuádriceps.
14 603 El tratamiento se realizará durante 4 sesiones (a razón de una sesión cada 14 días).
15 604

605 **RIESGOS**

606 La aplicación de las técnicas de punción utilizadas no han demostrado tener ningún
607 efecto secundario hasta la fecha, aunque el paciente puede experimentar dolor durante
608 y tras la punción, generalmente de uno o dos días de duración.
609

610 **RESPONSABILIDADES DEL PARTICIPANTE**

611 La información que usted posea sobre su estado de salud o sobre sensaciones
612 previas anormales al realizarle una punción, puede afectar la seguridad o el valor de
613 estas pruebas. La rápida comunicación por su parte de las sensaciones que
614 experimenta al realizar esta prueba es también de gran importancia. Usted es
615 responsable de revelar esa información al personal de la prueba cuando se le pregunte.
616

617 **PREGUNTAS**

618 Le animamos a que haga cualquier pregunta sobre los procedimientos seguidos o sus
619 resultados en la prueba. Si tiene alguna preocupación o pregunta, por favor pídasenos
620 más información, para ello le dejamos un correo electrónico mapilr86@hotmail.com y un
621 número de teléfono móvil: 616102365.
622

1
2
3 623 **LIBERTAD PARA DAR EL CONSENTIMIENTO**
4

5 624 Usted participa en el estudio de manera voluntaria, pudiendo abandonarlo en el
6 625 momento que considere oportuno, sin que esto conlleve ninguna repercusión negativa
7 para usted.
8
9 626

10
11 627 Los datos obtenidos en el estudio serán confidenciales y únicamente se hará uso
12 de ellos para el cumplimiento de los objetivos planteados en la investigación. No se
13 628 cederán estos datos a terceros sin el consentimiento expreso de los sujetos
14 629 participantes a quienes pertenezcan los datos.
15
16 630

17
18 631 En esta investigación se garantizará el anonimato de los sujetos que aportan los
19 632 datos, estableciendo un código disociado para identificarlos que sólo será conocido por
20 633 los responsables de la realización del trabajo de campo.
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29
30 637 Fdo: M^a Pilar López Royo
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3 652 - **MODELO DE CONSENTIMIENTO INFORMADO**

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9
10 656 **Título del PROYECTO: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN**
11 657 **PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”**

12
13 658 Doña: M^a Pilar López Royo (mapilr86@hotmail.com)

14
15 659 Departamento de Fisiatría y Enfermería

16
17 660 **UNIVERSIDAD DE ZARAGOZA**

18 661

19
20 662 **Yo, (nombre y apellidos del participante)**

21
22 663 He recibido suficiente información en relación con el proyecto, he leído la hoja de
23 664 información que se me ha entregado y he podido hacer preguntas sobre el proyecto,
24 665 recibiendo respuestas satisfactorias.

25
26 666 Entiendo que la participación es voluntaria y que puedo abandonar el proyecto:

27
28 667 . Cuando lo desee

29
30 668 . Sin tener que dar explicaciones

31
32 669 . Sin que esto repercuta en mis cuidados médicos

33
34 670

35
36 671 He sido claramente informado de forma clara y precisa del tratado que recibirán mis
37 672 datos personales que se contienen en este proyecto, sabiendo que los datos serán
38 673 tratados y custodiados bajo mi intimidad y a la vigente normativa de la protección de
39 674 datos, y que sobre estos datos me asisten los derechos de rectificación, acceso y
40 675 oposición comunicándolo al investigador principal que figura en este consentimiento.

41
42 676

43
44 677 Declaro que presto libremente mi conformidad para participar en el estudio.

45
46 678

47
48 679 Deseo ser informado sobre los resultados del estudio: sí no (marque lo que
49 680 proceda)

50
51 681

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2
3 682 Así pues, acepto que las muestras derivadas de este proyecto puedan ser utilizadas en
4 683 futuras investigaciones siempre y cuando están relacionadas con ésta.

5
6
7 684

8
9 685 Por lo tanto, doy mi conformidad para que mis datos clínicos sean revisados por
10 686 personal ajeno al centro, para los fines del estudio, y soy consciente de que este
11 687 consentimiento es revocable.

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20 Firma del participante:

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22 _____

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25 Fecha:

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34 692 He explicado la naturaleza y el propósito del proyecto al paciente mencionado

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39 Firma del Investigador:

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53 695 Consentimiento informado estudio_____

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55 696 Versión_____, fecha_____

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3 **1 Appendix D. Checklist SPIRIT**
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6 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and
7 related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1-2
	2b	All items from the World Health Organization Trial Registration Data Set	1-2
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	19-20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	19
	5b	Name and contact information for the trial sponsor	19
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6-7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10-11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11

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4	Implemen	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
5	tation			
6	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
7	(masking)			
8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
9				
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13	Methods: Data collection, management, and analysis			
14				
15	Data	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12
16	collection			
17	methods			
18		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
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20				
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23	Data	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
24	management			
25				
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27				
28				
29				
30	Statistical	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
31	methods			
32		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12-13
33				
34		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12-13
35				
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40	Methods: Monitoring			
41				
42	Data	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-
43	monitoring			
44		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-
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51	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-
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55	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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58	Ethics and dissemination			
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4	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
5			
6			
7	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
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9			
10			
11	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
12			
13		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
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17	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
18			
19			
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21	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
22			
23	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
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26			
27	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
28			
29			
30	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
31			
32		31b	Authorship eligibility guidelines and any intended use of professional writers
33			
34		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
35			
36			
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40	Appendices		
41			
42	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
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45	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable
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BMJ Open

A comparative study of three treatment interventions for patellar tendinopathy: a protocol for a randomized controlled trial

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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Eccentric Exercise, Tendinopathy, Percutaneous Needle Electrolysis, Dry Needling

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3 A comparative study of three treatment interventions for patellar tendinopathy: a
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5 protocol for a randomized controlled trial
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8 López-Royo MP^{a,b}, Gómez-Trullén EM^b, Ortiz-Lucas M^a, Galán-Díaz RM^a, Bataller-Cervero
9
10 AV^a, Al-Boloushi Z^{b,c}, Hamam-Alcober Y^a, Herrero P^{a*}
11
12

13 **AFFILIATIONS**
14

- 15
16 **A.** iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov.
17 A23 km 299, 50830. Villanueva de Gállego, Zaragoza, Spain.
18
19 **B.** Universidad de Zaragoza. Facultad de Ciencias de la Salud. Dpto. de Fisiatría y
20 Enfermería. C/ Domingo Miral s/n, 50009 - Zaragoza, Spain.
21
22 **A.** Ministry of Health, State of Kuwait. Jamal Abdunnasser Street, Al Solaibeykhat
23 Area 5. Kuwait City. Safat 13001.
24
25
26
27
28
29
30
31
32

33 ***CORRESPONDENCE TO:**
34

35
36 Dr. Pablo Herrero. iPhysio Research Group. Universidad San Jorge. Campus
37 Universitario, Autov A23, Km 299, 50830 Villanueva de Gállego, Zaragoza, Spain.
38
39 Tel.: (+34) 976 060 100 Fax: 976 077 581. Email: pherrero@usj.es
40
41
42

43 **ADDITIONAL AUTHOR INFORMATION**
44

45
46 Maria Pilar López Royo. Emails: mplopez@usj.es
47

48
49 Eva María Gómez Trullén. Email: evagomez@unizar.es
50

51
52 María Ortiz Lucas. Email: mariaortizlucas@gmail.com
53

54
55 Rita María Galán Díaz. Email: rmgalan@usj.es
56

57
58 Ana Vanessa Bataller-Cervero. Email: avbataller@usj.es
59
60

1
2
3 Yasmina Hamam-Alcober. Email: yhamam@usj.es
4
5

6 Zaid AL-boloushi. Email: boloushi@me.com
7
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12 **WORD COUNT:** 3924words.
13
14
15

16 17 **ABSTRACT**

18
19 **Introduction:** Patellar tendinopathy is a degenerative disease of the patellar tendon,
20 which affects athletes from a variety of sports, and is especially predominant in sports
21 involving high-impact jumping. The aim of this study is to compare the effectiveness of
22 needling therapies in order to determine the most effective treatment protocol of patellar
23 tendinopathy.
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31 **Methods and analysis:** This study is a randomized controlled trial with blinded
32 participants. Measurements will be carried out by a specially trained blinded assessor. A
33 sample of 57 patients with a medical diagnosis of patellar tendinopathy will participate
34 in this study and will be divided into three treatment groups. Eligible participants will be
35 randomly allocated to receive either: (a) treatment group with Percutaneous Needle
36 Electrolysis, (b) treatment group with Dry Needling or (c) treatment group with placebo
37 needling. In addition, all groups will perform eccentric exercise. Functionality and muscle
38 strength parameters, pain, ultrasound appearances and patient perceived quality of life
39 shall be evaluated using the VISA-p, jump test, VAS, US images and SF-36, respectively.
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Participants will be assessed at baseline, at 10 weeks and at 22 weeks after baseline. The
expected findings will allow us to advance in the treatment of this injury as they will help
determine whether a needling intervention has additional effects on an eccentric exercise
program and whether any of the needling modalities is more effective than the other.

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3 **Ethics and dissemination:** This protocol has been approved by the Ethics Committee of
4 Aragon (N° PI15/0017). The trial will be conducted in accordance with the Declaration
5 of Helsinki.
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9 **Trial Registration Number:** NCT02498795.
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13 **Strengths and limitations of this study**

- 14 - This randomized clinical trial will report the effects on functionality and pain of three
15 different treatment interventions in both the short and long term.
- 16 - The double-blinded and placebo-control design will enhance objectivity and help reduce
17 bias.
- 18 - The effects of two minimally invasive treatments in physical therapy will be compared
19 for the first time in patellar tendinopathy.
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33 **INTRODUCTION**

34 Patellar tendinopathy (PT), also known as jumper's knee, is a degenerative condition
35 affecting the patellar tendon resulting in anterior knee pain associated with focal and
36 palpable tenderness at the inferior pole of the patella. This disorder has similar histologic
37 findings to other tendon disorders characterized by an increased thickness of the tendon
38 and changes in vascularity, and cellularity, with incompletely healed tendon micro-
39 ruptures and disturbed collagen distribution(1).
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49 This degenerative condition affects athletes from a variety of sports, and is especially
50 predominant in sports involving high-impact jumping. The overall prevalence of PT in
51 non-elite players is 8.5%, although this figure increases in sports that place high demands
52 on the patellar ligament, increasing up to 14.2% in volleyball athletes. Among elite
53 volleyball and basketball players, a prevalence of 45% and 32%, respectively, has been
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3 reported. In addition, jumper's knee is almost twice as common among male non-elite
4 athletes when compared with female athletes(2).
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7 The diagnosis is typically based on the clinical history and symptomatic findings.
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9 Currently, imaging techniques, such as color-Doppler ultrasound (CD-US) and gray scale
10 ultrasound (GS-US) can be used for the assessment of the patellar tendon to clinically
11 confirm the diagnosis(3).
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16 Treatments used for PT fall into two major groups. The first group comprises medical
17 treatments which include non-steroidal anti-inflammatory drugs (NSAIDs), platelet-rich
18 plasma injection(4) and autologous growth factors(5). The second group consists of
19 physical therapies, including both conservative and invasive approaches (needling
20 techniques).
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28 Conservative therapies are generally accepted as the first line of approach for managing
29 PT(6, 7), considering exercise as the gold standard of treatment, either eccentric exercise
30 (EE) or high slow resistance training programs. Both had demonstrated similar
31 effectiveness in the treatment of PT(6-8). In 2012, EE was shown to be effective in the
32 treatment of tendinopathies at various locations of the body, including PT, and there was
33 a greater likelihood of clinical improvement when performed on a declined surface(6, 8,
34 9). In recent years, further evidence now supports the fact that exercise is more effective
35 than other conventional treatments in tendinopathy, such as iontophoresis, US, Cyriax
36 treatment, etc.(10).
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49 Physical therapy approaches for PT continue to evolve and a number of innovative
50 treatment options are now available, such as dry needling (DN)(11), electrotherapeutic
51 invasive modalities (e.g. electrolysis)(12-14) and extracorporeal shockwave (ECSW)
52 therapy(15). Recently, research has focused on regenerative therapies with high
53 expectations of success because some of these techniques seem to achieve a rapid
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3 regeneration of the injured tendon(11, 12, 16). However, evidence-based regenerative
4 therapies are limited and there is no agreement to date regarding which of these is the
5 most effective(17). DN consists of the insertion of a needle (filiform and solid, non-
6 beveled) with the aim of provoking a local injury leading to an inflammatory response
7 and the subsequent regeneration of the injured area in approximately one week. A study
8 performed by Abat et al. reported that DN induced histological and mechanical changes
9 in rat Achilles tendons at week one, with changes persisting at week four(18).
10 Percutaneous Needle Electrolysis (PNE) is an ultrasound-guided technique used by
11 physiotherapists consisting of causing localized lysis in the damaged and/or degenerated
12 tissue by means of a galvanic current transmitted through an acupuncture needle. This
13 technique may affect inflammatory mediators in damaged muscle tissue and influence the
14 new vascularization of the injured area in rats(18). James et al.(11) carried out a cohort
15 study in humans analyzing one group treated with DN and another treated with autologous
16 blood injections. In both cases, they found improvements compared to the baseline
17 measurements. However, this study failed to find differences between the different
18 treatments, concluding that both techniques were equally effective. In relation to PNE, a
19 former study(14) analyzed the treatment effect of electrolysis applied once a week in a
20 group of patients without any control or comparative group, reporting that patients
21 obtained statistically and clinically significant improvements compared to baseline
22 measurements.

23
24 From a biological point of view, it seems reasonable to hypothesize that a patient will
25 obtain benefits thanks to the mechanical effects provided by the needle, and that patients
26 may benefit more if the electrolysis effect is added to the mechanical stimuli provided by
27 the needle(16).
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3 Therefore, the aim of this study is to determine whether invasive techniques have
4 additional effects for the treatment of PT when compared with EE alone, and whether the
5 application of PNE provides any additional benefits aside from performing DN alone, in
6 the short and long term.
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15 **METHODS AND ANALYSIS**

17 **Study design**

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20 The trial is designed as a randomized, controlled, participant, investigator and outcomes
21 assessor blinded, experimental study, aimed at comparing three different physiotherapy
22 protocols applied in three intervention groups of PT patients. Randomization will be
23 performed as block randomization with a 1:1:1 allocation.
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29 This protocol follows the standards of the Helsinki Convention of good clinical practices.
30 The Ethics Committee of Aragon (CEICA) has evaluated the project and has given its
31 favorable opinion and support, N° PI15/0017 (Appendix 1).
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36 The study has been carried out following the SPIRIT statement for clinical trial protocol
37 and a SPIRIT Checklist has been included (Appendix 2).
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43 **Study setting**

44 After reviewing the literature and observing the high incidence of this pathology in
45 amateur young adults who perform sports and more specifically, jump sports, the search
46 of patients has been performed in sports clubs of basketball, football, volleyball, CrossFit,
47 and handball, together with running clubs and several gyms located in the city. A decision
48 was made to conduct the study in X, where the university is located, as well as the
49 laboratory to be used for assessments and treatments.
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3 The assessments will be conducted at the Motion Analysis laboratory of X, and the
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5 treatment will be performed at two different sites depending on the availability of both
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7 spaces and of schedules. Nonetheless, the same material will always be used.
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10 11 12 **Participants**

13 14 *Inclusion criteria*

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16 Participants eligible for inclusion in this study must meet the following criteria: 1. History
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18 of PT and anterior knee pain located on the inferior pole of the patella for over three
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20 months; 2. Aged between 18 and 45 years; 3. Palpation tenderness of the superior
21
22 insertion of the patellar tendon; 4. A score below 80 on the VISA-p questionnaire.
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24

25 26 *Exclusion criteria*

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28 Exclusion criteria for the study are: 1. Knee surgery within the previous six months; 2.
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30 Chronic joint diseases; 3. Corticosteroid injection in the patellar tendon within the
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32 previous three months; 4. Contraindications for needling; 5. Use of drugs 48 hours
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34 previously (e.g. NSAIDs); 6. Any other concomitant treatment for PT.
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40 41 **Methodology**

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43 In the first session, all participants will be instructed on how to perform a daily home
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45 program of EE. This will consist of performing three sets of 15 single leg squat repetitions
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47 on a decline board every day, according to Alfredson's protocol(19) increasing the speed
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49 if participants do not have pain. Participants will be informed that exercise is allowed to
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51 reach 5 in a numerical pain rating scale(20), and if it is higher then they will stop and
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53 notify the researcher, attempting once again 24 h later following the same rules.
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57 For the interventions, the participants will be placed in a supine position with a pillow
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59 under the knee (approximately 20° of knee flexion). The area will be cleansed with an
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3 antiseptic solution (70% Propan-2-ol, Skin-des). An ultrasound probe cover will be used
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5 during the intervention for infectious control. To determine the relevant treatment area,
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7 two factors will be considered: 1) Palpation of the areas exhibiting higher sensitivity and
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9 that reproduce the patient's symptoms; 2) Tendon areas showing degenerative changes
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11 assessed under ultrasound. Each group will receive a total of four sessions distributed
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13 throughout eight weeks of treatment, once every two weeks.
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19 *DN intervention combined with EE (DN-G) and PNE intervention combined with EE*
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21 *(PNE-G)*
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23 Specific DN needles will be used during needling treatments, (Agu-punt, Spain).
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25 Considering the thickness of the tendon and the approach, we shall use needles measuring
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27 0.25 x 25 mm. The procedure will be guided by US to ensure the specificity of application
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29 on the injured area and to guarantee that the procedure is safe for the patient. The DN
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31 needle will reach the relevant treatment area (areas with degenerative PT changes). Each
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33 session will consist of three needle insertions lasting three seconds each. In PNE-G
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35 applications, an intensity of 3 mA galvanic current will be used during the three seconds
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37 that the procedure lasts. The dose of 3 mA has demonstrated to be as effective as 6 mA
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39 in the treatment of tendinopathy injuries in animal models(18) as a result, the lower dose
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41 was selected for this study.
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49 *Control group (CG)*
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51 A sham needle will be placed upon the treatment zone, simulating the same procedure as
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53 the rest of participants enrolled in the other groups. The needle will be placed in a specific
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55 holder and will be manipulated during the intervention to simulate a real treatment. This
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holder will have a cover over the bottom part of the same in order to avoid the needle contacting the skin.

Outcomes

Baseline data

Baseline data will include gender, age, height, weight, body-mass index, affected side, level, sports and frequency of physical activity, duration of symptoms, medication and previous rehabilitation treatments and infiltrations received. A blinded observer will assess all participants at baseline, 10 weeks and 22 weeks after baseline. Participants will be asked to inform the researchers if there were any changes in medication or if they are receiving any other treatment or infiltration during the study.

Primary outcome measure

Participants will complete the VISA-p questionnaire at baseline. The VISA-p questionnaire is designed to measure the severity of PT(21). The VISA-p score is the primary outcome variable. This scale consists of eight questions, the first six questions of which employ an analogical visual scale in order to assign a score of 0 to 10, where 10 represents the optimum state, for the purpose of quantifying pain and function in different activities, whereas the last two questions assess the level of functionality and ability to perform physical activity.

Secondary outcome measure

At the first evaluation, participants will complete the Visual Analog Scale (VAS), considering the level of pain they feel while practicing their sport's activity. Participants will be explained that a score of 0 indicates the absence of pain whereas a score of 10 represents the maximum tolerable pain. They will also complete a questionnaire to assess their quality of life (SF-36)(22).

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3 In order to assess tendon structure, an US evaluation using ultrasound equipment (Logic
4 S7 Expert, General Electric Healthcare) and a linear probe (MLG-15 5–10 MHz) will be
5 used. The ultrasonographic assessment protocol will be carried out according to the
6 Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European
7 Society of Musculoskeletal Radiology(23). The ultrasonographic assessment will consist
8 of a longitudinal sequence from the tendon origin to the insertion and transverse sections
9 on the pole of the patella, the tendon body and its insertion on the tibial tuberosity, with
10 the subject in supine position, with 20° knee flexion, and a pillow under the knee. The
11 presence of degenerative signs compatible with the medical diagnosis of PT (thickness of
12 the tendon, hypoechoic areas, irregularities affecting the cortical bone, calcifications) that
13 could be relevant for the selection of the target area will also be assessed. In addition,
14 CD-US assessment will be carried out to detect the presence of hypervascularization, with
15 the subject in supine position and with the knee relaxed in full extension, in order to obtain
16 further information to specifically define the target area.
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35 Upon completion of the evaluation, a jump test will be carried out, measured with a force
36 platform (FP4060-10-2000, Bertec Corporation). In this evaluation, subjects will warm
37 up during 5 minutes on a treadmill, subsequently, they will perform dynamic stretches for
38 the leg muscles. The Jump test will be explained to participants and they will be asked to
39 demonstrate how they will perform the assessment to ensure that they have understood it
40 before going to the platform. Later, patients will go to the platform forces and will
41 perform each jump 3 times (squat jump, Abalakov jump and countermovement jump test)
42 with 60 seconds between jumps and 2 minutes between different jumps (Table 1)(24-26).
43 The maximum height of the jump will be analyzed via the measurement of the flight time
44 recorded on the force platforms, the eccentric power and the maximum concentric force
45 performed. The Abalakov jump will be performed with the subject standing in an upright
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3 position with a full arm swing. A rapid downward movement will be immediately
4 followed by a rapid upward vertical movement as high as possible, all in one sequence.
5
6 The same procedure will be applied for the CMJ jump, however, this test will be
7 performed with the hands on the hips to avoid arm swings. Finally, a Squat Jump will be
8 performed with 90 degrees of flexion of the knee.
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17 **Participant timeline**

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19 The study design will be a double-blind randomized controlled trial. The flow chart of
20 the trial is shown in Figure 1 and the check list SPIRIT schedule is shown in Figure 2.
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26 **'Patient and Public Involvement'**

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28 Patients who had PT were not involved in setting the research question or the outcome
29 measures, however the concept of patient involvement translated to the execution phases
30 of the research. Patients and their families were central to the dissemination of the
31 information, which helped to recruit study participants. We intend to disseminate the main
32 results to trial participants and will seek patient and public involvement in the
33 development of an appropriate method of dissemination.
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45 **Sample size**

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47 Regarding the sample size, a calculation of statistical power was made prior to the study.
48
49 Accepting an alpha risk of 0.05 and a beta risk in a bilateral contrast, 19 subjects are
50 needed in every treatment group to detect a difference equal or superior to 15 points on
51 the VISA-p scale and assuming a standard deviation of 15 points(27). The estimated rate
52 of loss to follow-up is 20%.
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3 Recruitment of subjects for the trial will take place between October 2018 and March
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5 2020 and will be carried out by means of informative campaigns targeted at different
6
7 Sports Clubs and Federations by means of e-mail and advertisements in the different
8
9 University mass media.

10
11
12 The interested subjects will receive an e-mail explaining the inclusion and exclusion
13
14 criteria, as well as the purpose of the study. *If they meet the defined criteria, they will be*
15
16 *invited to send us their medical diagnosis.*

21 **Recruitment**

22
23 Participants will be recruited from sports clubs by the physiotherapist or the coach.
24
25 Contact has been made with various orthopedists who will collaborate with recruitment,
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27 so that when they establish a diagnosis of this pathology in their examination room they
28
29 can refer us to the patients for their recruitment to the study.
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35 **Allocation**

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34 Participants will be randomly assigned to either CG or DN-G or PNE-G with a 1:1:1
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36 allocation using an opaque envelope, with a block size of fifteen participants (5 for each
37
38 group).
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42 Sealed opaque randomization envelopes with a study-specific participant number will be
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44 supplied by an external statistician. A colleague not involved in the research study will
45
46 take the sealed opaque numbered envelopes in order, by number, and deliver the correct
47
48 envelope to the treating physical therapist. The envelope will contain a piece of paper,
49
50 which will be labelled with the same participant specific number, plus the group
51
52 assignment (PNE-G, DN-G or CG).
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3 Participants who fulfill the inclusion criteria will receive the standardized oral and written
4 information, and, once they grant their consent to take part in the trial, they will be
5
6 randomized into the three groups.
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10 11 12 **Blinding**

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14 Assessments regarding clinical recovery will be conducted by an assessor blinded to
15 treatment allocation. Due to the nature of the intervention, participants can be blinded to
16 allocation. Patients will be explained that they are going to receive a needling treatment,
17 that it may be a bit painful, and that if at any moment they are unable to tolerate the pain
18 they must inform the researcher to stop the intervention. In order to blind patients, all the
19 interventions were made with the ultrasound and the PNE device connected to simulate
20 the same intervention in all groups. In contrast, the physiotherapist performing the
21 intervention cannot be blinded, however will be instructed not to disclose the allocation
22 status of the participant at any time or during the follow up assessments. An employee
23 outside the research team will feed data into the computer in separate datasheets so that
24 the researchers can analyze data without having access to information about the
25 allocation.
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42 With the intention of evaluating patient blinding, an online questionnaire will be sent to
43 participants upon completion of the study, asking them about the treatment they received.
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49 **Data collection methods**

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51 For the data collection of the participants, an oral questionnaire will be used containing
52 questions targeted at collecting baseline data and information concerning the pathology.
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3 Different questionnaires and assessment scales (VISA-p, VAS, SF-36) in Spanish will
4 be given to each participant in paper when they attend the assessment, and they will be
5 granted sufficient time to complete the same.
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10 11 12 **Data management and statistical analysis** 13

14 In this study, all data will be entered electronically in the assessment room.

15
16 Original scales and questionnaires will be entered and kept on a locked file at the
17 participating site.
18

19 Participant files are to be stored in numerical order and stored in a secure and accessible
20 place and manner. Participant files will be maintained in storage for a period of 2 years
21 after completion of the study.
22
23

24 The statistical analysis will be carried out by an intention-to-treat analysis. Variables will
25 be described in number (percentage) and average (standard deviation) or median
26 (interquartile range) attending to their distribution. Quantitative variables will be
27 analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine
28 correct statistical tests according to these results.
29
30

31 Outcomes will be analyzed using mixed linear and logistic regression models considering
32 participants as a random effect and group of treatment as fixed factors. Baseline
33 characteristics will be introduced in the model as covariance. Numbers needed to treat
34 index will also be calculated. The primary aim of the analysis will be to calculate the
35 difference obtained in the VISA-p score after the intervention (final measurement - initial
36 measurement). Finally, the magnitude of the effect of the result shall be calculated and
37 therefore its clinical importance, by means of the following formula:
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$$40 \quad I^* = \sqrt{\frac{F(1,dfR)}{F(1,dfR) + dfR}}$$

41 The significance level set for all the analysis will be $p \leq 0.05$.
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ETHICS AND DISEMINATION

The study design, procedures and informed consent procedure were approved and consequently the study will be carried out in compliance with the Helsinki Declaration of Human Rights. All participants will have to provide written Spanish informed consent.

Appendix A.

The trial's results will be published in peer-reviewed international journals or otherwise made publicly available and will be presented at national and international conferences and symposiums irrespective of the outcomes.

Any modifications to the protocol, which may impact the study procedures, potential patient benefits or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be approved by the Ethics Committee prior to implementation and notified to the health authorities in accordance with local regulations.

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored identified by code number. All local databases will be secured with password-protected access systems.

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

DISCUSSION

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3 This study seeks to investigate the effects of physiotherapy needling techniques on pain,
4
5 functionality and quality of life in PT.
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7
8 PT is a common cause of knee pain in cases of degeneration of the patellar tendon. Among
9
10 the causes of PT, extrinsic factors (e.g., patellar tendon loading with exercise) and
11
12 intrinsic factors (e.g., malalignment, high patella, imbalances) have been proposed(28).
13
14 Traditionally, the focus has been on quadriceps strengthening exercises and many reviews
15
16 have shown that the effect of the treatment could be estimated to give the patients a 50-
17
18 70% change of improvement on pain and functionality(6, 29, 30).
19

20
21 Regarding needling treatment, previous studies have shown a great improvement in PT
22
23 using PNE in combination with EE, with all patients reporting an improvement at least
24
25 one month after treatment(12-14, 18). This is an improvement compared to the minimum
26
27 three months needed to improve symptoms by applying other conventional techniques
28
29 (pharmacological and biological treatments, cold/heat techniques, shock waves, etc.)
30
31 Additionally, in a long-term study conducted in 2013, this technique was shown to
32
33 improve symptoms quickly and steadily for at least 10 years(31). These findings
34
35 demonstrate that this technique ensures that patients remain pain-free for a long period.
36
37 Furthermore, we were only able to find four articles(12-14, 18) addressing the application
38
39 of PNE for the recovery of PT, however, none of the articles studied were RCTs, which
40
41 entail limited evidence of the effectiveness of this technique.
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47 In addition, there are no standardized protocols for the application of PNE, which explains
48
49 the great variability in the number of sessions and application time based on the literature.
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51 Therefore, this study aims to facilitate clinical practice and combine the available
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53 methodology criteria in the application of this promising technique.
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56 Regarding DN, the literature shows many similarities with PNE, since there is only one
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58 RCT that compares functionality improvements among patients who have received PRP.
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3 This study reflected that in the short term PRP had better results for pain and functionality,
4
5 however, DN was more effective than PRP after six months(32).
6

7
8 For the application of both needling techniques, US-guidance is normally used to be able
9
10 to observe firstly the presentation of the tendon, and later to observe the needle and enable
11
12 a much more specific treatment approach. However, US has disadvantages including its
13
14 operator dependence and the limited ability to rule out intra-articular disease. The
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16 sensitivity and specificity of ultrasonography for patellar tendinopathy is between 58%
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18 and 94%, respectively(33).
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21 Moreover, functionality of the tendon is usually measured with the VISA-p(34, 35),
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23 whereas jump tests (representing a similar action to that performed in subject's daily
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25 sports) are only evaluated in a few papers(25, 36). Countermovement jumps and squat
26
27 jumps are the most reliable and valid field tests for the estimation of the explosive power
28
29 of the lower limbs in physically active men(37). Thus, we will combine both, in order to
30
31 be more accurate in the assessment of the tendon's functionality, and be able to assess
32
33 changes that may affect their sport performance.
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37 This study has several strengths. First, we will evaluate two techniques that currently lack
38
39 strong evidence. However, in doing so, we are contributing to new knowledge in the field
40
41 of the recovery of musculoskeletal injuries. Second, the role of invasive techniques will
42
43 be determined by comparing the effects between these techniques and a control group.
44
45 The reliability of data is ensured, as both patients and the assessor will be blinded. Third,
46
47 a sub-analysis with US will be performed to investigate changes in the presence of
48
49 calcifications, cortical irregularities, neovascularization, thickness, eco-intensity, eco-
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51 variation and eco-texture of the patellar tendon.
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3 However, there are some limitations to this study. Blinding of the physiotherapist
4 performing the intervention is not possible. Furthermore, follow-up is limited to 22 weeks
5 after baseline.
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10 The findings obtained may help advance the treatment of this injury by identifying the
11 most effective treatment protocol and to avoid the associated consequences, such as the
12 prevention of relapses and reducing the potential impact on the musculoskeletal system.
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AUTHOR'S CONTRIBUTIONS

MPL, EMG and PH conceived of the idea, and developed the intervention. MPL and PH

JUMP TEST PROTOCOL	
5-minute warm-up consisting of steady jogging on a treadmill	
Dynamic Stretches lasting 5 minutes, as instructed by the physical therapist	Psoas Quadriceps Gluteus maximus Gastrocnemius Hamstring muscles

wrote the article. MPL, MO, RMG, AVB, ZA, YH and PH developed the design of the trial. MO were involved in development of the statistical analysis of the trial and contributed to the content of the article. AVB contributed to the design and writing of the jump test protocol. All authors have read and approved the final manuscript.

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COMPETING INTEREST STATEMENT

The authors declare that they have no competing interests.

TABLES

Table 1. Jump test's protocol.

<p>Three jump tests are performed</p> <ul style="list-style-type: none"> - 3 jumps off the ground for 3 times for the patient to become familiar with the tests - The subject is placed on the platform and asked to perform each test 3 times, with 60 seconds rest between the different tests 	<p>Abalakov test</p> <p>Countermovement jump test</p> <p>Squat jump</p>
<p>The highest jump is selected for the study</p>	

FIGURES

Figure 1. Flow diagram. Randomized controlled trial design.

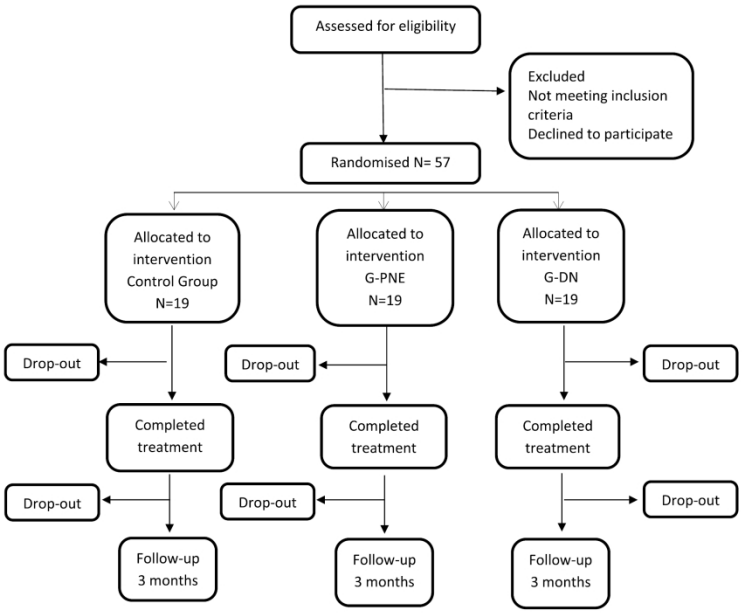
G-PNE: Percutaneous Needle Electrolysis Group. G-DN: Dry Needle Group.

Figure 2. Schedule for the enrolment and intervention.

Schedule for enrolment and intervention per cluster. -t1: baseline; t1–t2: intervention period; t2: 8 weeks after baseline; t3: 10 weeks after baseline; t4: 3 months after baseline. G-PNE: Percutaneous Needle Electrolysis Group; G-DN: Dry Needle Group; US: ultrasound.

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Figure 1. Flow diagram. Randomized controlled trial design.



210x297mm (300 x 300 DPI)

Figure 2. Schedule for enrolment and intervention.

	Enrolment	Allocation	Close-out			
TIMEPOINT**	-t ₁	0	t ₁	t ₂	t ₃	t ₄
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
<i>Control group</i>			↔			
<i>G-PNE</i>			↔			
<i>G-DN</i>			↔			
ASSESSMENTS:						
<i>Baseline demographic information</i>	X					
<i>VISA-P</i>	X		X		X	X
<i>VAS</i>			X		X	X
<i>SF-36</i>			X		X	X
<i>Tendon structure US</i>			X		X	X
<i>Jump test</i>			X		X	X

215x279mm (300 x 300 DPI)

DOCUMENTO DE INFORMACIÓN AL PACIENTE

Fecha:

Título del proyecto: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Investigador principal:

Doña: M^a Pilar López Royo

Este estudio se basa en el estudio comparativo de tres tratamientos que utilizan distintas técnicas de fisioterapia invasiva junto con un programa de ejercicio excéntrico para el tratamiento de la tendinopatía rotuliana. Por medio del tratamiento se produce una disminución del dolor asociado a esta patología y un aumento de la fuerza de la pierna, lo que a su vez hace que mejore la funcionalidad en las actividades de la vida diaria y mejore la calidad de vida.

PROCESO DE SELECCIÓN DE PACIENTES

Criterios de inclusión:

- Edad comprendida entre 18 y 40 años.
- Practicar cualquier deporte de forma habitual.
- Pacientes con diagnóstico médico de tendinopatía rotuliana crónica con un mínimo de 3 meses de evolución y con sintomatología.
- Dolor a la palpación del tendón en el polo inferior de la rótula y durante el entrenamiento o competición.
- Puntuación del cuestionario VISA-P menor de 80 (el resultado obtenido de rellenar el cuestionario tiene que ser menor de 80 puntos de los 100 posibles para poder participar en el estudio).

Criterios de exclusión:

- Paciente operado de la rodilla afectada en los últimos 6 meses.
- Infiltraciones en la rodilla afectada en los últimos 3 meses.
- Paciente que ha recibido tratamiento farmacológico o fisioterápico en las últimas 48 horas o durante el estudio.
- Patología con menos de 3 meses de evolución.
- Presentar tendinopatía rotuliana bilateral.
- Puntuación del cuestionario VISA-p mayor o igual de 80 (el resultado obtenido de rellenar el cuestionario no puede ser igual o superar los 80 puntos de los 100 posibles, sino no podrá participar en el estudio).
- Imposibilidad para aplicar alguna de las técnicas de tratamiento o valoración por

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2 contraindicación absoluta o relativa.
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7 **PROCEDIMIENTO**

8 El tratamiento consiste en realizar un protocolo de ejercicios excéntricos de cuádriceps que
9 realizará en casa de forma diaria, y que serán revisados con el fisioterapeuta para valorar su
10 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
11 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
12 según el protocolo de tratamiento propuesto de forma totalmente **aleatorizada** y según los
13 criterios diagnósticos específicos de la misma, siguiendo las indicaciones, criterios de aplicación y
14 criterios diagnósticos.
15 criterios diagnósticos.

16 Son técnicas de punción cuyo objetivo es producir una respuesta inflamatoria aguda que active los
17 mecanismos fisiológicos de regeneración del tejido y mejorar el dolor y la funcionalidad en la
18 articulación de la rodilla, se realiza con agujas de punción seca, similares a las agujas de
19 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
20 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
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26 Los registros serán realizados en el Espacio de Valoración Funcional de la Universidad San Jorge,
27 en la Facultad de Ciencias de la Salud, Edificio III. Se pondrá a su disposición la posibilidad de
28 utilizar el autobús que utiliza el personal y alumnado de la universidad (en el horario que éste esté
29 disponible). Las fechas y horarios serán convenidas con cada participante en función de su
30 disponibilidad y la de los investigadores, buscando la conformidad de todos. La duración
31 aproximada del estudio para cada paciente será de 30 minutos, aunque este horario podrá variar
32 en función de los acontecimientos.
33 en función de los acontecimientos.
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39 Será recibido por los miembros del equipo de investigación y una vez allí, se le realizará un primer
40 análisis fisioterápico, rellenará una encuesta, una escala analógica visual (EVA) del dolor y el
41 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.
42 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.

43 Tras éste primer registro se le colocará un marcador pasivo en el pantalón. Se le pedirá que
44 realice el siguiente protocolo:
45 realice el siguiente protocolo:

- 46 - Calentamiento de 5 minutos en cinta a ritmo constante.
- 47 - Estiramientos dinámicos de psoas, cuádriceps, glúteo, gastrocnemios, isquiotibiales durante 5
- 48 minutos instruidos por el fisioterapeuta.
- 49 - Realización de los 3 saltos fuera de la plataforma durante 3 veces para que se familiarice con los
- 50 tests.
- 51 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 52 con contramovimiento (CMJ) y el squatjump (SJ).
- 53 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 54 con contramovimiento (CMJ) y el squatjump (SJ).
- 55 con contramovimiento (CMJ) y el squatjump (SJ).
- 56 con contramovimiento (CMJ) y el squatjump (SJ).
- 57 con contramovimiento (CMJ) y el squatjump (SJ).
- 58 con contramovimiento (CMJ) y el squatjump (SJ).
- 59 con contramovimiento (CMJ) y el squatjump (SJ).
- 60 con contramovimiento (CMJ) y el squatjump (SJ).

60 Se colocará en la plataforma y realizará 3 saltos de cada uno de los test con una separación entre
ellos de 60 segundos.

Se valora el tendón por ecografía, y se recogen datos por medio de personal adiestrado y se envía

1 a personal especialista en radiodiagnóstico.

2
3 Tras los registros de los saltos se dará por finalizada la valoración.

4
5
6 Tras la 1ª valoración, se realizará una división en tres grupos de los pacientes de forma
7 aleatorizada.

8
9 Se le realizará el protocolo de tratamiento de fisioterapia invasiva que le haya correspondido.
10 Realizará una sesión del tratamiento cada 14 días, y se realizará la 2ª valoración 1 semana más
11 tarde de la 4ª sesión de punción para valorar los cambios que se hayan producido tras el
12 tratamiento, repitiéndose de nuevo el proceso de recogida de datos realizado al inicio del estudio.
13 Se realizará un seguimiento a los tres meses de la valoración post-tratamiento para valorar la
14 eficacia de la técnica a largo plazo del tratamiento.

15
16 El procedimiento se realizará guiado ecográficamente para asegurar la especificidad de aplicación
17 sobre la zona relevante de tratamiento y garantizar la seguridad de la técnica. Se hace posterior a
18 esta intervención una serie de ejercicios excéntricos de cuádriceps. El tratamiento se realizará
19 durante 4 sesiones (a razón de una sesión cada 14 días).

20 21 22 **RIESGOS**

23 La aplicación de las técnicas de punción utilizadas no han demostrado tener ningún efecto
24 secundario hasta la fecha, aunque el paciente puede experimentar dolor durante y tras la punción,
25 generalmente de uno o dos días de duración.

26 27 28 **RESPONSABILIDADES DEL PARTICIPANTE**

29 La información que usted posea sobre su estado de salud o sobre sensaciones previas
30 anormales al realizarle una punción, puede afectar la seguridad o el valor de estas pruebas. La
31 rápida comunicación por su parte de las sensaciones que experimenta al realizar esta prueba es
32 también de gran importancia. Usted es responsable de revelar esa información al personal de la
33 prueba cuando se le pregunte.

34 35 36 **PREGUNTAS**

37 Le animamos a que haga cualquier pregunta sobre los procedimientos seguidos o sus resultados
38 en la prueba. Si tiene alguna preocupación o pregunta, por favor pídaenos más información, para
39 ello le dejamos un correo electrónico mapilr86@hotmail.com y un número de teléfono móvil:
40 616102365.

41 42 43 **LIBERTAD PARA DAR EL CONSENTIMIENTO**

44 Usted participa en el estudio de manera voluntaria, pudiendo abandonarlo en el momento
45 que considere oportuno, sin que esto conlleve ninguna repercusión negativa para usted.

46 Los datos obtenidos en el estudio serán confidenciales y únicamente se hará uso de ellos

1
2 para el cumplimiento de los objetivos planteados en la investigación. No se cederán estos datos a
3 terceros sin el consentimiento expreso de los sujetos participantes a quienes pertenezcan los
4 datos.
5

6 En esta investigación se garantizará el anonimato de los sujetos que aportan los datos,
7 estableciendo un código disociado para identificarlos que sólo será conocido por los responsables
8 de la realización del trabajo de campo.
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17 Fdo: M^a Pilar López Royo
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MODELO DE CONSENTIMIENTO INFORMADO

Título del PROYECTO: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Doña: M^a Pilar López Royo (mapilr86@hotmail.com)
Departamento de Fisiatría y Enfermería
UNIVERSIDAD DE ZARAGOZA

Yo, (nombre y apellidos del participante)

He recibido suficiente información en relación con el proyecto, he leído la hoja de información que se me ha entregado y he podido hacer preguntas sobre el proyecto, recibiendo respuestas satisfactorias.

Entiendo que la participación es voluntaria y que puedo abandonar el proyecto:

- . Cuando lo desee
- . Sin tener que dar explicaciones
- . Sin que esto repercuta en mis cuidados médicos

He sido claramente informado de forma clara y precisa del tratado que recibirán mis datos personales que se contienen en este proyecto, sabiendo que los datos serán tratados y custodiados bajo mi intimidad y a la vigente normativa de la protección de datos, y que sobre estos datos me asisten los derechos de rectificación, acceso y oposición comunicándolo al investigador principal que figura en este consentimiento.

Declaro que presto libremente mi conformidad para participar en el estudio.

Deseo ser informado sobre los resultados del estudio: sí no (marque lo que proceda)

Así pues, acepto que las muestras derivadas de este proyecto puedan ser utilizadas en futuras investigaciones siempre y cuando están relacionadas con ésta.

Por lo tanto, doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno al centro, para los fines del estudio, y soy consciente de que este consentimiento es

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2 revocable.
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7 Firma del participante:

8 _____
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10 Fecha:

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17 He explicado la naturaleza y el propósito del proyecto al paciente mencionado
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21 Firma del Investigador:

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24 Fecha:

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31 Consentimiento informado estudio _____

32 Versión _____, fecha _____
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3 **Appendix 2. Checklist SPIRIT**
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6 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and
7 related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1-3
	2b	All items from the World Health Organization Trial Registration Data Set	2-3
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	22
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5-6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13

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4	Implemen	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
5	tation			
6	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
7	(masking)			
8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
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13	Methods: Data collection, management, and analysis			
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15	Data	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-14
16	collection			
17	methods			
18		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
19				
20				
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23	Data	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
24	management			
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30	Statistical	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
31	methods			
32		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
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34		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
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39	Methods: Monitoring			
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42	Data	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-
43	monitoring			
44		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-
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51	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-
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54	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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58	Ethics and dissemination			
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Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

8

BMJ Open

A comparative study of three treatment interventions for patellar tendinopathy: a protocol for a randomized controlled trial

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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine, Pathology
Keywords:	Eccentric Exercise, Tendinopathy, Percutaneous Needle Electrolysis, Dry Needling

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A comparative study of three treatment interventions for patellar tendinopathy: a
protocol for a randomized controlled trial

López-Royo MP^{a,b}, Gómez-Trullén EM^b, Ortiz-Lucas M^a, Galán-Díaz RM^a, Bataller-Cervero
AV^a, Al-Boloushi Z^{b,c}, Hamam-Alcober Y^a, Herrero P^{a*}

AFFILIATIONS

- A.** iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov. A23 km 299, 50830. Villanueva de Gállego, Zaragoza, Spain.
- B.** Universidad de Zaragoza. Facultad de Ciencias de la Salud y del Deporte. Dpto. de Fisiatría y Enfermería. C/ Domingo Miral s/n, 50009 - Zaragoza, Spain.
- A.** Ministry of Health, State of Kuwait. Jamal Abdunnasser Street, Al Solaibeykhat Area 5. Kuwait City. Safat 13001.

*CORRESPONDENCE TO:

Dr. Pablo Herrero. iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov A23, Km 299, 50830 Villanueva de Gállego, Zaragoza, Spain.
Tel.: (+34) 976 060 100 Fax: 976 077 581. Email: pherrero@usj.es

ADDITIONAL AUTHOR INFORMATION

Maria Pilar López Royo. Emails: mplopez@usj.es

Eva María Gómez Trullén. Email: evagomez@unizar.es

María Ortiz Lucas. Email: mariaortizlucas@gmail.com

Rita María Galán Díaz. Email: rmgalan@usj.es

Ana Vanessa Bataller-Cervero. Email: avbataller@usj.es

1
2
3 Yasmina Hamam-Alcober. Email: yhamam@usj.es
4
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6 Zaid AL-boloushi. Email: boloushi@me.com
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12 **WORD COUNT:** 3985 words.
13
14
15

16 17 **ABSTRACT**

18
19 **Introduction:** Patellar tendinopathy is a degenerative disease of the patellar tendon,
20 which affects athletes from a variety of sports, and is especially predominant in sports
21 involving high-impact jumping. The aim of this study is to compare the effectiveness of
22 three therapies in order to determine the most effective treatment protocol of patellar
23 tendinopathy.
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31 **Methods and analysis:** This study is a randomized controlled trial with blinded
32 participants. Measurements will be carried out by a specially trained blinded assessor. A
33 sample of 57 patients with a medical diagnosis of patellar tendinopathy will participate
34 in this study and will be divided into three treatment groups. Eligible participants will be
35 randomly allocated to receive either: (a) treatment group with Percutaneous Needle
36 Electrolysis, (b) treatment group with Dry Needling or (c) treatment group with placebo
37 needling. In addition, all groups will perform eccentric exercise. Functionality and muscle
38 strength parameters, pain, ultrasound appearances and patient perceived quality of life
39 shall be evaluated using the VISA-p, jump test, VAS, US images and SF-36, respectively.
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Participants will be assessed at baseline, at 10 weeks and at 22 weeks after baseline. The
expected findings will allow us to advance in the treatment of this injury, as they will help
determine whether a needling intervention has additional effects on an eccentric exercise
program and whether any of the needling modalities is more effective than the other.

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3 **Ethics and dissemination:** This protocol has been approved by the Ethics Committee of
4 Aragon (N° PI15/0017). The trial will be conducted in accordance with the Declaration
5 of Helsinki.
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9 **Trial Registration Number:** NCT02498795.
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13 **Strengths and limitations of this study**

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17 - This randomized clinical trial will report the effects on functionality and pain of three
18 different treatment interventions in both the short and long term.
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21 - The double-blinded and placebo-control design will enhance objectivity and help reduce
22 bias.
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25 - The effects of two minimally invasive treatments in physical therapy will be compared
26 for the first time in patellar tendinopathy.
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33 **INTRODUCTION**

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35 Patellar tendinopathy (PT), also known as jumper's knee, is a degenerative condition
36 affecting the patellar tendon resulting in anterior knee pain associated with focal and
37 palpable tenderness at the inferior pole of the patella. This disorder has similar histologic
38 findings to other tendon disorders characterized by an increased thickness of the tendon
39 and changes in vascularity, and cellularity, with incompletely healed tendon micro-
40 ruptures and disturbed collagen distribution(1).
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49 This degenerative condition affects athletes from a variety of sports, and is especially
50 predominant in sports involving high-impact jumping. The overall prevalence of PT in
51 non-elite players is 8.5%, although this figure increases in sports that place high demands
52 on the patellar ligament, increasing up to 14.2% in volleyball athletes. Among elite
53 volleyball and basketball players, a prevalence of 45% and 32%, respectively, has been
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3 reported. In addition, jumper's knee is almost twice as common among male non-elite
4 athletes when compared with female athletes(2).
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6
7 The diagnosis is typically based on the clinical history and symptomatic findings.
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9 Currently, imaging techniques, such as color-Doppler ultrasound (CD-US) and gray scale
10 ultrasound (GS-US) can be used for the assessment of the patellar tendon to clinically
11 confirm the diagnosis(3).
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15
16 Treatments used for PT fall into two major groups. The first group comprises medical
17 treatments which include non-steroidal anti-inflammatory drugs (NSAIDs), platelet-rich
18 plasma injection(4) and autologous growth factors(5). The second group consists of
19 physical therapies, including both conservative and invasive approaches (needling
20 techniques).
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29 Conservative therapies are generally accepted as the first line of approach for managing
30 PT(6, 7), considering exercise as the gold standard of treatment, either eccentric exercise
31 (EE) or high slow resistance training programs. Both have demonstrated similar
32 effectiveness in the treatment of PT(6-8). In 2012, EE was shown to be effective in the
33 treatment of tendinopathies at various locations of the body, including PT, with a greater
34 likelihood of clinical improvement when performed on a declined surface(6, 8, 9). In
35 recent years, further evidence now supports the fact that exercise is more effective than
36 other conventional treatments in tendinopathy, such as iontophoresis, US, Cyriax
37 treatment, etc.(10).
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50 Physical therapy approaches for PT continue to evolve and a number of innovative
51 treatment options are now available, such as dry needling (DN)(11), electrotherapeutic
52 invasive modalities (e.g. electrolysis)(12-14) and extracorporeal shockwave (ECSW)
53 therapy(15). Recently, research has focused on regenerative therapies with high
54 expectations of success because some of these techniques seem to achieve a rapid
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3 regeneration of the injured tendon(11, 12, 16). However, evidence-based regenerative
4 therapies are limited and there is no agreement to date regarding which of these is the
5 most effective(17). DN consists of the insertion of a needle (filiform and solid, non-
6 beveled) with the aim of provoking a local injury leading to an inflammatory response
7 and the subsequent regeneration of the injured area in approximately one week. A study
8 performed by Abat et al. reported that DN induced histological and mechanical changes
9 in rat Achilles tendons at week one, with changes persisting at week four(18).
10 Percutaneous Needle Electrolysis (PNE) is an ultrasound-guided technique used by
11 physiotherapists consisting of causing localized lysis in the damaged and/or degenerated
12 tissue by means of a galvanic current transmitted through an acupuncture needle. This
13 technique may affect inflammatory mediators in damaged muscle tissue and influence the
14 new vascularization of the injured area in rats(18). James et al.(11) carried out a cohort
15 study in humans analyzing one group treated with DN and another treated with autologous
16 blood injections. In both cases, they found improvements compared to the baseline
17 measurements. However, this study failed to find differences between the different
18 treatments, concluding that both techniques were equally effective. In relation to PNE, a
19 former study(14) analyzed the treatment effect of electrolysis applied once a week in a
20 group of patients without any control or comparative group, reporting that patients
21 obtained statistically and clinically significant improvements compared to baseline
22 measurements.

23
24 From a biological point of view, it seems reasonable to hypothesize that a patient will
25 obtain benefits thanks to the mechanical effects provided by the needle(16), and that
26 patients may benefit more if the electrolysis effect is added to the mechanical stimuli
27 provided by the needle(19).
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3 Therefore, the aim of this study is to determine which intervention is the most effective,
4 and whether invasive techniques have additional effects for the treatment of PT when
5 compared with EE alone. Moreover, whether the application of PNE provides any
6 additional benefits aside from performing DN alone, in the short and long term.
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15 **METHODS AND ANALYSIS**

16 **Study design**

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18 The trial is designed as a randomized, controlled, participant, investigator and outcomes
19 assessor blinded, experimental study, aimed at comparing three different physiotherapy
20 protocols applied in three intervention groups of PT patients. Randomization will be
21 performed as block randomization with a 1:1:1 allocation.
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29 This protocol follows the standards of the Helsinki Convention of good clinical practices.
30 The Ethics Committee of Aragon (CEICA) has evaluated the project and has given its
31 favorable opinion and support, N° PI15/0017 (Appendix 1).
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36 The study has been carried out following the SPIRIT statement for clinical trial protocol
37 and a SPIRIT Checklist has been included (Appendix 2).
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43 **Study setting**

44 After reviewing the literature and observing the high incidence of this pathology in
45 amateur young adult athletes who perform sports and more specifically, jump sports,
46 patient recruitment has been performed in basketball, football, volleyball, CrossFit, and
47 handball sports clubs, together with running clubs and several gyms located in the city. A
48 decision was made to conduct the study in X, where the university is located, as well as
49 the laboratory to be used for assessments and treatments.
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3 The assessments will be conducted at the Motion Analysis laboratory of X, and the
4
5 treatment will be performed at two different sites depending on the availability of both
6
7 spaces and of schedules. Nonetheless, the same material will always be used.
8
9

10 11 12 **Participants**

13 14 *Inclusion criteria*

15
16 Participants eligible for inclusion in this study must meet the following criteria: 1. History
17
18 of PT and anterior knee pain located on the inferior pole of the patella for over three
19
20 months; 2. Aged between 18 and 45 years; 3. Palpation tenderness of the superior
21
22 insertion of the patellar tendon; 4. A score below 80 on the VISA-p questionnaire.
23
24

25 26 *Exclusion criteria*

27
28 Exclusion criteria for the study are: 1. Knee surgery within the previous six months; 2.
29
30 Chronic joint diseases; 3. Corticosteroid injection in the patellar tendon within the
31
32 previous three months; 4. Contraindications for needling; 5. Use of drugs 48 hours
33
34 previously (e.g. NSAIDs); 6. Any other concomitant treatment for PT.
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40 41 **Methodology**

42
43 In the first session, all participants will be instructed on how to perform a daily home
44
45 program of EE. This will consist of performing three sets of 15 single leg squat repetitions
46
47 on a decline board every day, according to Alfredson's protocol(20) increasing the speed
48
49 if participants do not have pain. Participants will be informed that exercise is allowed to
50
51 reach 5 in a numerical pain rating scale(21), and if it is higher then they will stop and
52
53 notify the researcher, attempting once again 24 h later following the same rules.
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57 For the interventions, the participants will be placed in a supine position with a pillow
58
59 under the knee (approximately 20° of knee flexion). The area will be cleansed with an
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3 antiseptic solution (70% Propan-2-ol, Skin-des). An ultrasound probe cover will be used
4
5 during the intervention for infectious control. To determine the relevant treatment area,
6
7 two factors will be considered: 1) Palpation of the areas exhibiting higher sensitivity and
8
9 that reproduce the patient's symptoms; 2) Tendon areas showing degenerative changes
10
11 assessed under ultrasound. Each group will receive a total of four sessions distributed
12
13 throughout eight weeks of treatment, once every two weeks.
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19 *DN intervention combined with EE (DN-G) and PNE intervention combined with EE*
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21 *(PNE-G)*
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23 Specific DN needles will be used during needling treatments, (Agu-punt, Spain).
24
25 Considering the thickness of the tendon and the approach, we shall use needles measuring
26
27 0.25 x 25 mm. The procedure will be guided by US to ensure the specificity of application
28
29 on the injured area and to guarantee that the procedure is safe for the patient. The DN
30
31 needle will reach the relevant treatment area (areas with degenerative PT changes). Each
32
33 session will consist of three needle insertions lasting three seconds each. In PNE-G
34
35 applications, an intensity of 3 mA galvanic current will be used during the three seconds
36
37 that the procedure lasts(19). The dose of 3 mA has demonstrated to be as effective as 6
38
39 mA in the treatment of tendinopathy injuries in animal models(18,19). In humans, a study
40
41 conducted in 2016 showed that a dose of 3 mA in PT generated structural changes
42
43 compatible with tendon regeneration, together with improvement of functionality and
44
45 pain (22). In contrast, the same study found that lower doses were effective only for the
46
47 improvement of functionality and pain. As a result, a 3 mA dose was selected for this
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49 study.
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58 *Control group (CG)*
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3 A sham needle will be placed upon the treatment zone, simulating the same procedure as
4 the rest of participants enrolled in the other groups. The needle will be placed in a specific
5 holder and will be manipulated during the intervention to simulate a real treatment. This
6 holder will have a cover over the bottom part of the same in order to avoid the needle
7 contacting the skin.
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17 **Outcomes**

18 *Baseline data*

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21 Baseline data will include gender, age, height, weight, body-mass index, affected side,
22 level, sports and frequency of physical activity, duration of symptoms, medication and
23 previous rehabilitation treatments and infiltrations received. A blinded observer will
24 assess all participants at baseline, 10 weeks and 22 weeks after baseline. Participants will
25 be asked to inform the researchers if there were any changes in medication or if they are
26 receiving any other treatment or infiltration during the study.
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35 *Primary outcome measure*

36
37 Participants will complete the VISA-p questionnaire at baseline. The VISA-p
38 questionnaire is designed to measure the severity of PT(23). The VISA-p score is the
39 primary outcome variable. This scale consists of eight questions, the first six questions of
40 which employ an analogical visual scale in order to assign a score of 0 to 10, where 10
41 represents the optimum state, for the purpose of quantifying pain and function in different
42 activities, whereas the last two questions assess the level of functionality and ability to
43 perform physical activity.
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53 *Secondary outcome measure*

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55 During the first evaluation, participants will complete the Visual Analog Scale (VAS),
56 considering the level of pain they feel while practicing their sport's activity. Participants
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3 will be explained that a score of 0 indicates the absence of pain whereas a score of 10
4 represents the maximum tolerable pain. They will also complete a questionnaire to assess
5 their quality of life (SF-36)(24).
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9
10 In order to assess tendon structure, an US evaluation using ultrasound equipment (Logic
11 S7 Expert, General Electric Healthcare) and a linear probe (MLG-15 5–10 MHz) will be
12 used. The ultrasonographic assessment protocol will be carried out according to the
13 Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European
14 Society of Musculoskeletal Radiology(25). The ultrasonographic assessment will consist
15 of a longitudinal sequence from the tendon origin to the insertion and transverse sections
16 on the pole of the patella, the tendon body and its insertion on the tibial tuberosity, with
17 the subject in supine position, with 20° knee flexion, and a pillow under the knee. The
18 presence of degenerative signs compatible with the medical diagnosis of PT (thickness of
19 the tendon, hypoechoic areas, irregularities affecting the cortical bone, calcifications) that
20 could be relevant for the selection of the target area will also be assessed. In addition,
21 CD-US assessment will be carried out to detect the presence of hypervascularization, with
22 the subject in supine position and with the knee relaxed in full extension, in order to obtain
23 further information to specifically define the target area.
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42 Upon completion of the evaluation, a jump test will be carried out, measured with a force
43 platform (FP4060-10-2000, Bertec Corporation). In this evaluation, subjects will warm
44 up during 5 minutes on a treadmill, subsequently, they will perform dynamic stretches for
45 the leg muscles. The Jump test will be explained to participants and they will be asked to
46 demonstrate how they will perform the assessment to ensure that they have understood it
47 before going to the platform. Later, patients will go to the platform forces and will
48 perform each jump 3 times (squat jump, Abalakov jump and countermovement jump test)
49 with 60 seconds between jumps and 2 minutes between different jumps (Table 1)(26-28).
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3 The maximum height of the jump will be analyzed via the measurement of the flight time
4 recorded on the force platforms, the eccentric power and the maximum concentric force
5 performed. The Abalakov jump will be performed with the subject standing in an upright
6 position with a full arm swing. A rapid downward movement will be immediately
7 followed by a rapid upward vertical movement as high as possible, all in one sequence.
8 The same procedure will be applied for the CMJ jump, however, this test will be
9 performed with the hands on the hips to avoid arm swings. Finally, a Squat Jump will be
10 performed with 90 degrees of flexion of the knee.
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24 **Participant timeline**

25
26 The study design will be a double-blind randomized controlled trial. The flow chart of
27 the trial is shown in Figure 1 and the check list SPIRIT schedule is shown in Figure 2.
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33 **'Patient and Public Involvement'**

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35 Patients with PT were not involved in setting the research question or the outcome
36 measures, however the concept of patient involvement translated to the execution phases
37 of the research. Patients and their families were central to the dissemination of the
38 information, which helped to recruit study participants. We intend to disseminate the main
39 results to trial participants and will seek patient and public involvement in the
40 development of an appropriate method of dissemination.
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51 **Sample size**

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53 Regarding the sample size, a calculation of statistical power was made prior to the study.
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55 Accepting an alpha risk of 0.05 and a beta risk in a bilateral contrast, 19 subjects are
56 needed in every treatment group to detect a difference equal or superior to 15 points on
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3 the VISA-p scale and assuming a standard deviation of 15 points(29). The estimated rate
4
5 of loss to follow-up is 20%.

6
7 Recruitment of subjects for the trial will take place between October 2018 and March
8
9 2020 and will be carried out by means of informative campaigns targeted at different
10
11 Sports Clubs and Federations by means of e-mail and advertisements in the different
12
13 University mass media.
14

15
16 The interested subjects will receive an e-mail explaining the inclusion and exclusion
17
18 criteria, as well as the purpose of the study. If they meet the defined criteria, they will be
19
20 invited to send us their medical diagnosis.
21
22

23 24 25 26 **Recruitment**

27
28 Participants will be recruited from sports clubs by the physiotherapist or the coach.
29
30 Contact has been made with various orthopedists who will collaborate with recruitment,
31
32 so that when they establish a diagnosis of this pathology in their examination room they
33
34 can refer us to the patients for their recruitment to the study.
35
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37 38 39 40 **Allocation**

41
42 Participants will be randomly assigned to either CG or DN-G or PNE-G with a 1:1:1
43
44 allocation using an opaque envelope, with a block size of fifteen participants (5 for each
45
46 group).
47

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49 Sealed opaque randomization envelopes with a study-specific participant number will be
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51 supplied by an external statistician. A colleague not involved in the research study will
52
53 take the sealed opaque numbered envelopes in order, by number, and deliver the correct
54
55 envelope to the treating physical therapist. The envelope will contain a piece of paper,
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3 which will be labelled with the same participant specific number, plus the group
4
5 assignment (PNE-G, DN-G or CG).
6

7
8 Participants who fulfill the inclusion criteria will receive the standardized oral and written
9
10 information, and, once they grant their consent to take part in the trial, they will be
11
12 randomized into the three groups.
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16 17 **Blinding**

18
19 Assessments regarding clinical recovery will be conducted by an assessor blinded to
20
21 treatment allocation. Due to the nature of the intervention, participants can be blinded to
22
23 allocation. Patients will be explained that they are going to receive a needling treatment,
24
25 that it may be slightly painful, and that if at any time they are unable to tolerate the pain
26
27 they must inform the researcher to stop the intervention. In order to blind patients, all the
28
29 interventions were made with the ultrasound and the PNE device connected to simulate
30
31 the same intervention in all groups. In contrast, the physiotherapist performing the
32
33 intervention cannot be blinded, however he/she will be instructed not to disclose the
34
35 allocation status of the participant at any time or during the follow up assessments. An
36
37 employee outside the research team will feed data into the computer in separate datasheets
38
39 so that the researchers can analyze data without having access to information about the
40
41 allocation.
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47 With the intention of evaluating patient blinding, an online questionnaire will be sent to
48
49 participants upon completion of the study, asking them about the treatment they received.
50
51

52 53 **Data collection methods**

54
55 For the data collection, an oral questionnaire will be used containing questions targeted
56
57 at collecting baseline data and information concerning the pathology.
58
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3 Different questionnaires and assessment scales (VISA-p, VAS, SF-36) in Spanish will
4
5 be given to each participant in paper when they attend the assessment, and they will be
6
7 granted sufficient time to complete the same.
8
9

12 **Data management and statistical analysis**

14 In this study, all data will be entered electronically in the assessment room.

16 Original scales and questionnaires will be entered and kept on a locked file at the
17
18 participating site.
19

21 Participant files are to be stored in numerical order and stored in a secure and accessible
22
23 place and manner. Participant files will be maintained in storage for a period of 2 years
24
25 after completion of the study.
26

28 The statistical analysis will be carried out by an intention-to-treat analysis. Variables will
29
30 be described in number (percentage) and average (standard deviation) or median
31
32 (interquartile range) attending to their distribution. Quantitative variables will be
33
34 analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine
35
36 correct statistical tests according to these results.
37
38

39 Outcomes will be analyzed using mixed linear and logistic regression models considering
40
41 participants as a random effect and group of treatment as fixed factors. Baseline
42
43 characteristics will be introduced in the model as covariance. Numbers needed to treat
44
45 index will also be calculated. The primary aim of the analysis will be to calculate the
46
47 difference obtained in the VISA-p score after the intervention (final measurement - initial
48
49 measurement). Finally, the magnitude of the effect of the result will be calculated and
50
51 therefore its clinical importance, by means of the following formula:
52
53

$$54 \quad I^* = \sqrt{\frac{F(1,dfR)}{F(1,dfR) + dfR}}$$

56 The significance level set for all the analysis will be $p \leq 0.05$.
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ETHICS AND DISEMINATION

The study design, procedures and informed consent procedure were approved and consequently the study will be carried out in compliance with the Helsinki Declaration of Human Rights. All participants will have to provide written Spanish informed consent.

Appendix 1.

The results for this trial will be published in peer-reviewed international journals or otherwise made publicly available and will be presented at national and international conferences and symposiums irrespective of the outcomes.

Any modifications to the protocol, which may impact the study procedures, potential patient benefits or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be approved by the Ethics Committee prior to implementation and notified to the health authorities in accordance with local regulations.

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored identified by code number. All local databases will be secured with password-protected access systems.

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

DISCUSSION

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3 This study seeks to investigate the effects of physiotherapy needling techniques on pain,
4
5 functionality and quality of life in PT.
6

7
8 PT is a common cause of knee pain in cases of degeneration of the patellar tendon. Among
9
10 the causes of PT, extrinsic factors (e.g., patellar tendon loading with exercise) and
11
12 intrinsic factors (e.g., malalignment, high patella, imbalances) have been proposed(30).
13
14 Traditionally, the focus has been on quadriceps strengthening exercises and many reviews
15
16 have shown that the effect of the treatment could be estimated to give the patients a 50-
17
18 70% change of improvement on pain and functionality(6, 32, 33).
19

20
21 Regarding needling treatment, previous studies have shown a great improvement in PT
22
23 using PNE in combination with EE, with all patients reporting an improvement at least
24
25 one month after treatment(12-14, 18). This is an improvement compared to the minimum
26
27 three months needed to improve symptoms by applying other conventional techniques
28
29 (pharmacological and biological treatments, cold/heat techniques, shock waves, etc.)
30
31 Additionally, in a long-term study conducted in 2013, this technique was shown to
32
33 improve symptoms quickly and steadily for at least 10 years(33). These findings
34
35 demonstrate that this technique ensures that patients remain pain-free for a long period.
36
37 Furthermore, we were only able to find four articles(12-14, 18) addressing the application
38
39 of PNE for the recovery of PT, however, none of the articles studied were RCTs, which
40
41 entail limited evidence of the effectiveness of this technique.
42
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46
47 In addition, there are no standardized protocols for the application of PNE, which explains
48
49 the great variability in the number of sessions and application time based on the literature.
50
51 Therefore, this study aims to facilitate clinical practice and combine the available
52
53 methodology criteria in the application of this promising technique.
54

55
56 Regarding DN, the literature shows many similarities with PNE, since there is only one
57
58 RCT that compares functionality improvements among patients who have received PRP.
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3 This study reflected that in the short term PRP had better results for pain and functionality,
4
5 however, DN was more effective than PRP after six months(34).
6

7
8 For the application of both needling techniques, US-guidance is normally used to be able
9
10 to observe firstly the presentation of the tendon, and later to observe the needle and enable
11
12 a much more specific treatment approach. However, US has disadvantages including its
13
14 operator dependence and the limited ability to rule out intra-articular disease. The
15
16 sensitivity and specificity of ultrasonography for patellar tendinopathy is between 58%
17
18 and 94%, respectively(35).
19

20
21 Moreover, functionality of the tendon is usually measured with the VISA-p(36,37),
22
23 whereas jump tests (representing a similar action to that performed in subject's daily
24
25 sports) are only evaluated in a few papers(27,38). Countermovement jumps and squat
26
27 jumps are the most reliable and valid field tests for the estimation of the explosive power
28
29 of the lower limbs in physically active men(39). Thus, we will combine both, in order to
30
31 be more accurate in the assessment of the tendon's functionality, and be able to assess
32
33 changes that may affect their sport performance.
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36
37 This study has several strengths. First, we will evaluate two techniques that currently lack
38
39 strong evidence. However, in doing so, we are contributing to new knowledge in the field
40
41 of the recovery of musculoskeletal injuries. Second, the role of invasive techniques will
42
43 be determined by comparing the effects between these techniques and a control group.
44
45 The reliability of data is ensured, as both patients and the assessor will be blinded. Third,
46
47 a sub-analysis with US will be performed to investigate changes in the presence of
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49 calcifications, cortical irregularities, neovascularization, thickness, eco-intensity, eco-
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51 variation and eco-texture of the patellar tendon.
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3 However, there are some limitations to this study. Blinding of the physiotherapist
4 performing the intervention is not possible. Furthermore, follow-up is limited to 22 weeks
5 after baseline.
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10 The findings obtained may help advance the treatment of this injury by identifying the
11 most effective treatment protocol and to avoid the associated consequences, such as the
12 prevention of relapses and reducing the potential impact on the musculoskeletal system.
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10 **AUTHOR'S CONTRIBUTIONS**

11 MPL, EMG and PH conceived of the idea, and developed the intervention. MPL and PH
12 wrote the article. MPL, MO, RMG, AVB, ZA, YH and PH developed the design of the
13 trial. MO were involved in development of the statistical analysis of the trial and
14 contributed to the content of the article. AVB contributed to the design and writing of the
15 jump test protocol. All authors have read and approved the final manuscript.
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27 **FUNDING STATEMENT**

28 This research received no specific grant from any funding agency in the public,
29 commercial or not-for-profit sectors.
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36 **COMPETING INTEREST STATEMENT**

37 The authors declare that they have no competing interests.
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3 **TABLES**
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5 Table 1. Jump test's protocol.
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JUMP TEST PROTOCOL	
5-minute warm-up consisting of steady jogging on a treadmill	
Dynamic Stretches lasting 5 minutes, as instructed by the physical therapist	Psoas Quadriceps Gluteus maximus Gastrocnemius Hamstring muscles
Three jump tests are performed - 3 jumps off the ground for 3 times for the patient to become familiar with the tests - The subject is placed on the platform and asked to perform each test 3 times, with 60 seconds rest between the different tests	Abalakov test Countermovement jump test Squat jump
The highest jump is selected for the study	

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41 **FIGURES**
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43 Figure 1. Flow diagram. Randomized controlled trial design.
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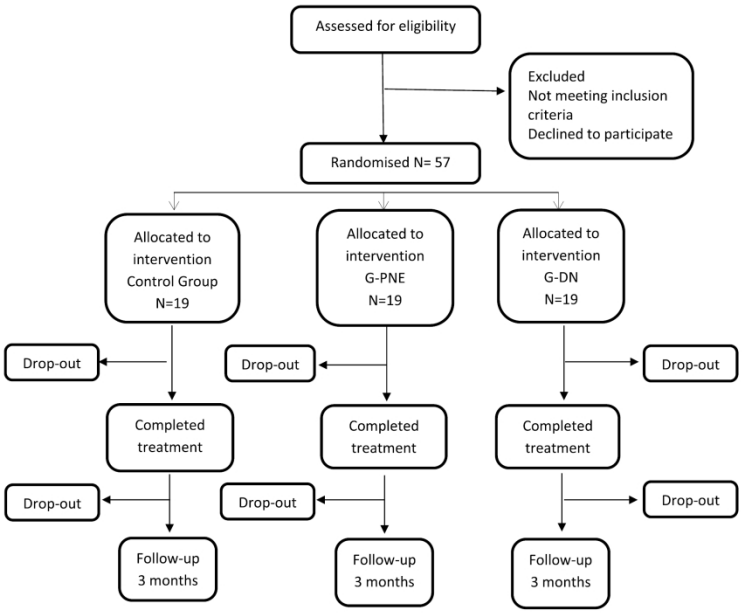
45 G-PNE: Percutaneous Needle Electrolysis Group. G-DN: Dry Needle Group.
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49 Figure 2. Schedule for the enrolment and intervention.
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51 Schedule for enrolment and intervention per cluster. -t1: baseline; t1-t2: intervention period; t2: 8 weeks
52 after baseline; t3: 10 weeks after baseline; t4: 3 months after baseline. G-PNE: Percutaneous Needle
53 Electrolysis Group; G-DN: Dry Needle Group; US: ultrasound.
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Figure 1. Flow diagram. Randomized controlled trial design.



210x297mm (300 x 300 DPI)

Figure 2. Schedule for enrolment and intervention.

	Enrolment	Allocation	Close-out			
TIMEPOINT**	-t ₁	0	t ₁	t ₂	t ₃	t ₄
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
<i>Control group</i>			↔			
<i>G-PNE</i>			↔			
<i>G-DN</i>			↔			
ASSESSMENTS:						
<i>Baseline demographic information</i>	X					
<i>VISA-P</i>	X		X		X	X
<i>VAS</i>			X		X	X
<i>SF-36</i>			X		X	X
<i>Tendon structure US</i>			X		X	X
<i>Jump test</i>			X		X	X

215x279mm (300 x 300 DPI)

DOCUMENTO DE INFORMACIÓN AL PACIENTE

Fecha:

Título del proyecto: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Investigador principal:

Doña: M^a Pilar López Royo

Este estudio se basa en el estudio comparativo de tres tratamientos que utilizan distintas técnicas de fisioterapia invasiva junto con un programa de ejercicio excéntrico para el tratamiento de la tendinopatía rotuliana. Por medio del tratamiento se produce una disminución del dolor asociado a esta patología y un aumento de la fuerza de la pierna, lo que a su vez hace que mejore la funcionalidad en las actividades de la vida diaria y mejore la calidad de vida.

PROCESO DE SELECCIÓN DE PACIENTES

Criterios de inclusión:

- Edad comprendida entre 18 y 40 años.
- Practicar cualquier deporte de forma habitual.
- Pacientes con diagnóstico médico de tendinopatía rotuliana crónica con un mínimo de 3 meses de evolución y con sintomatología.
- Dolor a la palpación del tendón en el polo inferior de la rótula y durante el entrenamiento o competición.
- Puntuación del cuestionario VISA-P menor de 80 (el resultado obtenido de rellenar el cuestionario tiene que ser menor de 80 puntos de los 100 posibles para poder participar en el estudio).

Criterios de exclusión:

- Paciente operado de la rodilla afectada en los últimos 6 meses.
- Infiltraciones en la rodilla afectada en los últimos 3 meses.
- Paciente que ha recibido tratamiento farmacológico o fisioterápico en las últimas 48 horas o durante el estudio.
- Patología con menos de 3 meses de evolución.
- Presentar tendinopatía rotuliana bilateral.
- Puntuación del cuestionario VISA-p mayor o igual de 80 (el resultado obtenido de rellenar el cuestionario no puede ser igual o superar los 80 puntos de los 100 posibles, sino no podrá participar en el estudio).
- Imposibilidad para aplicar alguna de las técnicas de tratamiento o valoración por

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2 contraindicación absoluta o relativa.
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7 **PROCEDIMIENTO**

8 El tratamiento consiste en realizar un protocolo de ejercicios excéntricos de cuádriceps que
9 realizará en casa de forma diaria, y que serán revisados con el fisioterapeuta para valorar su
10 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
11 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
12 según el protocolo de tratamiento propuesto de forma totalmente **aleatorizada** y según los
13 criterios diagnósticos específicos de la misma, siguiendo las indicaciones, criterios de aplicación y
14 criterios diagnósticos.
15 criterios diagnósticos.

16 Son técnicas de punción cuyo objetivo es producir una respuesta inflamatoria aguda que active los
17 mecanismos fisiológicos de regeneración del tejido y mejorar el dolor y la funcionalidad en la
18 articulación de la rodilla, se realiza con agujas de punción seca, similares a las agujas de
19 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
20 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
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26 Los registros serán realizados en el Espacio de Valoración Funcional de la Universidad San Jorge,
27 en la Facultad de Ciencias de la Salud, Edificio III. Se pondrá a su disposición la posibilidad de
28 utilizar el autobús que utiliza el personal y alumnado de la universidad (en el horario que éste esté
29 disponible). Las fechas y horarios serán convenidas con cada participante en función de su
30 disponibilidad y la de los investigadores, buscando la conformidad de todos. La duración
31 aproximada del estudio para cada paciente será de 30 minutos, aunque este horario podrá variar
32 en función de los acontecimientos.
33 en función de los acontecimientos.
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39 Será recibido por los miembros del equipo de investigación y una vez allí, se le realizará un primer
40 análisis fisioterápico, rellenará una encuesta, una escala analógica visual (EVA) del dolor y el
41 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.
42 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.

43 Tras éste primer registro se le colocará un marcador pasivo en el pantalón. Se le pedirá que
44 realice el siguiente protocolo:
45 realice el siguiente protocolo:

- 46 - Calentamiento de 5 minutos en cinta a ritmo constante.
- 47 - Estiramientos dinámicos de psoas, cuádriceps, glúteo, gastrocnemios, isquiotibiales durante 5
- 48 minutos instruidos por el fisioterapeuta.
- 49 - Realización de los 3 saltos fuera de la plataforma durante 3 veces para que se familiarice con los
- 50 tests.
- 51 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 52 con contramovimiento (CMJ) y el squatjump (SJ).
- 53 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 54 con contramovimiento (CMJ) y el squatjump (SJ).
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- 59 con contramovimiento (CMJ) y el squatjump (SJ).
- 60 con contramovimiento (CMJ) y el squatjump (SJ).

60 Se colocará en la plataforma y realizará 3 saltos de cada uno de los test con una separación entre
ellos de 60 segundos.

Se valora el tendón por ecografía, y se recogen datos por medio de personal adiestrado y se envía

1 a personal especialista en radiodiagnóstico.

2
3 Tras los registros de los saltos se dará por finalizada la valoración.

4
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6 Tras la 1ª valoración, se realizará una división en tres grupos de los pacientes de forma
7 aleatorizada.

8
9 Se le realizará el protocolo de tratamiento de fisioterapia invasiva que le haya correspondido.
10 Realizará una sesión del tratamiento cada 14 días, y se realizará la 2ª valoración 1 semana más
11 tarde de la 4ª sesión de punción para valorar los cambios que se hayan producido tras el
12 tratamiento, repitiéndose de nuevo el proceso de recogida de datos realizado al inicio del estudio.
13 Se realizará un seguimiento a los tres meses de la valoración post-tratamiento para valorar la
14 eficacia de la técnica a largo plazo del tratamiento.

15
16 El procedimiento se realizará guiado ecográficamente para asegurar la especificidad de aplicación
17 sobre la zona relevante de tratamiento y garantizar la seguridad de la técnica. Se hace posterior a
18 esta intervención una serie de ejercicios excéntricos de cuádriceps. El tratamiento se realizará
19 durante 4 sesiones (a razón de una sesión cada 14 días).

20 21 22 **RIESGOS**

23 La aplicación de las técnicas de punción utilizadas no han demostrado tener ningún efecto
24 secundario hasta la fecha, aunque el paciente puede experimentar dolor durante y tras la punción,
25 generalmente de uno o dos días de duración.

26 27 28 **RESPONSABILIDADES DEL PARTICIPANTE**

29 La información que usted posea sobre su estado de salud o sobre sensaciones previas
30 anormales al realizarle una punción, puede afectar la seguridad o el valor de estas pruebas. La
31 rápida comunicación por su parte de las sensaciones que experimenta al realizar esta prueba es
32 también de gran importancia. Usted es responsable de revelar esa información al personal de la
33 prueba cuando se le pregunte.

34 35 36 **PREGUNTAS**

37 Le animamos a que haga cualquier pregunta sobre los procedimientos seguidos o sus resultados
38 en la prueba. Si tiene alguna preocupación o pregunta, por favor pídanos más información, para
39 ello le dejamos un correo electrónico mapilr86@hotmail.com y un número de teléfono móvil:
40 616102365.

41 42 43 44 45 **LIBERTAD PARA DAR EL CONSENTIMIENTO**

46 Usted participa en el estudio de manera voluntaria, pudiendo abandonarlo en el momento
47 que considere oportuno, sin que esto conlleve ninguna repercusión negativa para usted.

48 Los datos obtenidos en el estudio serán confidenciales y únicamente se hará uso de ellos

1
2 para el cumplimiento de los objetivos planteados en la investigación. No se cederán estos datos a
3 terceros sin el consentimiento expreso de los sujetos participantes a quienes pertenezcan los
4 datos.
5

6 En esta investigación se garantizará el anonimato de los sujetos que aportan los datos,
7 estableciendo un código disociado para identificarlos que sólo será conocido por los responsables
8 de la realización del trabajo de campo.
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17 Fdo: M^a Pilar López Royo
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MODELO DE CONSENTIMIENTO INFORMADO

Título del PROYECTO: “ESTUDIO COMPARATIVO ENTRE 3 TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Doña: M^a Pilar López Royo (mapilr86@hotmail.com)
Departamento de Fisiatría y Enfermería
UNIVERSIDAD DE ZARAGOZA

Yo, (nombre y apellidos del participante)

He recibido suficiente información en relación con el proyecto, he leído la hoja de información que se me ha entregado y he podido hacer preguntas sobre el proyecto, recibiendo respuestas satisfactorias.

Entiendo que la participación es voluntaria y que puedo abandonar el proyecto:

- . Cuando lo desee
- . Sin tener que dar explicaciones
- . Sin que esto repercuta en mis cuidados médicos

He sido claramente informado de forma clara y precisa del tratado que recibirán mis datos personales que se contienen en este proyecto, sabiendo que los datos serán tratados y custodiados bajo mi intimidad y a la vigente normativa de la protección de datos, y que sobre estos datos me asisten los derechos de rectificación, acceso y oposición comunicándolo al investigador principal que figura en este consentimiento.

Declaro que presto libremente mi conformidad para participar en el estudio.

Deseo ser informado sobre los resultados del estudio: sí no (marque lo que proceda)

Así pues, acepto que las muestras derivadas de este proyecto puedan ser utilizadas en futuras investigaciones siempre y cuando están relacionadas con ésta.

Por lo tanto, doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno al centro, para los fines del estudio, y soy consciente de que este consentimiento es

1
2 revocable.
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7 Firma del participante:

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10 Fecha:

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17 He explicado la naturaleza y el propósito del proyecto al paciente mencionado
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21 Firma del Investigador:

22 _____
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24 Fecha:

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31 Consentimiento informado estudio _____

32 Versión _____, fecha _____
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3 **Appendix 2. Checklist SPIRIT**
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6 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and
7 related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1-3
	2b	All items from the World Health Organization Trial Registration Data Set	2-3
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	22
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5-6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13

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4	Implemen	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
5	tation			
6	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
7	(masking)			
8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
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13	Methods: Data collection, management, and analysis			
14				
15	Data	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-14
16	collection			
17	methods			
18		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
19				
20				
21				
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23	Data	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
24	management			
25				
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27				
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30	Statistical	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
31	methods			
32		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
33				
34		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
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39	Methods: Monitoring			
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41				
42	Data	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-
43	monitoring			
44		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-
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51	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-
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54	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
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58	Ethics and dissemination			
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Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

8

BMJ Open

A comparative study of treatment interventions for patellar tendinopathy: a protocol for a randomized controlled trial

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Complete List of Authors:	Lopez-Royo, Maria Pilar; Universidad San Jorge Facultad de Ciencias de la Salud; Universidad de Zaragoza, Facultad de Ciencias de la Salud y del Deporte Gómez-Trullén, Eva Maria; Universidad de Zaragoza, Facultad de Ciencias de la Salud y del Deporte Ortiz-Lucas, Maria; Universidad San Jorge Facultad de Ciencias de la Salud Galán-Díaz, Rita Maria; Universidad San Jorge Facultad de Ciencias de la Salud Bataller-Cervero, Ana Vanessa; Universidad San Jorge Facultad de Ciencias de la Salud Al-Boloushi, Zaid; Universidad de Zaragoza Facultad de Ciencias, Facultad de Ciencias de la Salud y del Deporte; Kuwait Ministry of Health Hamam-Alcober, Yasmina; Universidad San Jorge Facultad de Ciencias de la Salud, Fisioterapia Herrero, Pablo; Universidad San Jorge Facultad de Ciencias de la Salud
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3 A comparative study of treatment interventions for patellar tendinopathy: a protocol for
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5 a randomized controlled trial
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8 López-Royo MP^{a,b}, Gómez-Trullén EM^b, Ortiz-Lucas M^a, Galán-Díaz RM^a, Bataller-Cervero
9
10 AV^a, Al-Boloushi Z^{b,c}, Hamam-Alcober Y^a, Herrero P^{a*}
11
12

13 **AFFILIATIONS**
14

- 15
16 **A.** iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov.
17 A23 km 299, 50830. Villanueva de Gállego, Zaragoza, Spain.
18
19 **B.** Universidad de Zaragoza. Facultad de Ciencias de la Salud y del Deporte. Dpto.
20 de Fisiatría y Enfermería. C/ Domingo Miral s/n, 50009 - Zaragoza, Spain.
21
22 **A.** Ministry of Health, State of Kuwait. Jamal Abdunnasser Street, Al Solaibeykhat
23 Area 5. Kuwait City. Safat 13001.
24
25
26
27
28
29
30
31
32

33 ***CORRESPONDENCE TO:**
34

35
36 Dr. Pablo Herrero. iPhysio Research Group. Universidad San Jorge. Campus
37 Universitario, Autov A23, Km 299, 50830 Villanueva de Gállego, Zaragoza, Spain.
38
39 Tel.: (+34) 976 060 100 Fax: 976 077 581. Email: pherrero@usj.es
40
41
42

43 **ADDITIONAL AUTHOR INFORMATION**
44

45
46 Maria Pilar López Royo. Emails: mplopez@usj.es
47
48

49 Eva María Gómez Trullén. Email: evagomez@unizar.es
50
51

52 María Ortiz Lucas. Email: mariaortizlucas@gmail.com
53
54

55 Rita María Galán Díaz. Email: rmgalan@usj.es
56
57

58 Ana Vanessa Bataller-Cervero. Email: avbataller@usj.es
59
60

1
2
3 Yasmina Hamam-Alcober. Email: yhamam@usj.es
4
5

6 Zaid AL-boloushi. Email: boloushi@me.com
7
8
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12 **WORD COUNT:** 3967 words.
13
14
15

16 17 **ABSTRACT**

18
19 **Introduction:** Patellar tendinopathy is a degenerative disease of the patellar tendon,
20 which affects athletes from a variety of sports, and is especially predominant in sports
21 involving high-impact jumping. The aim of this study is to compare the effectiveness of
22 three therapies in order to determine the most effective treatment protocol of patellar
23 tendinopathy.
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31 **Methods and analysis:** This study is a randomized controlled trial with blinded
32 participants. Measurements will be carried out by a specially trained blinded assessor. A
33 sample of 57 patients with a medical diagnosis of patellar tendinopathy will participate
34 in this study and will be divided into three treatment groups. Eligible participants will be
35 randomly allocated to receive either: (a) treatment group with Percutaneous Needle
36 Electrolysis, (b) treatment group with Dry Needling or (c) treatment group with placebo
37 needling. In addition, all groups will perform eccentric exercise. Functionality and muscle
38 strength parameters, pain, ultrasound appearances and patient perceived quality of life
39 shall be evaluated using the VISA-p, jump test, VAS, US images and SF-36, respectively.
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Participants will be assessed at baseline, at 10 weeks and at 22 weeks after baseline. The
expected findings will allow us to advance in the treatment of this injury, as they will help
determine whether a needling intervention has additional effects on an eccentric exercise
program and whether any of the needling modalities is more effective than the other.

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3 **Ethics and dissemination:** This protocol has been approved by the Ethics Committee of
4 Aragon (N° PI15/0017). The trial will be conducted in accordance with the Declaration
5 of Helsinki.
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9 **Trial Registration Number:** NCT02498795.
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12 13 14 **Strengths and limitations of this study**

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16
17 - This randomized clinical trial will report the effects on functionality and pain of three
18 different treatment interventions in both the short and long term.
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21 - The double-blinded and placebo-control design will enhance objectivity and help reduce
22 bias.
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25 - The effects of two minimally invasive treatments in physical therapy will be compared
26 for the first time in patellar tendinopathy.
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33 **INTRODUCTION**

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35 Patellar tendinopathy (PT), also known as jumper's knee, is a degenerative condition
36 affecting the patellar tendon resulting in anterior knee pain associated with focal and
37 palpable tenderness at the inferior pole of the patella. This disorder has similar histologic
38 findings to other tendon disorders characterized by an increased thickness of the tendon
39 and changes in vascularity, and cellularity, with incompletely healed tendon micro-
40 ruptures and disturbed collagen distribution(1).
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49 This degenerative condition affects athletes from a variety of sports, and is especially
50 predominant in sports involving high-impact jumping. The overall prevalence of PT in
51 non-elite players is 8.5%, although this figure increases in sports that place high demands
52 on the patellar ligament, increasing up to 14.2% in volleyball athletes. Among elite
53 volleyball and basketball players, a prevalence of 45% and 32%, respectively, has been
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3 reported. In addition, jumper's knee is almost twice as common among male non-elite
4 athletes when compared with female athletes(2).

7 The diagnosis is typically based on the clinical history and symptomatic findings.
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9 Currently, imaging techniques, such as color-Doppler ultrasound (CD-US) and gray scale
10 ultrasound (GS-US) can be used for the assessment of the patellar tendon to clinically
11 confirm the diagnosis(3).
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16 Treatments used for PT fall into two major groups. The first group comprises medical
17 treatments which include non-steroidal anti-inflammatory drugs (NSAIDs), platelet-rich
18 plasma injection(4) and autologous growth factors(5). The second group consists of
19 physical therapies, including both conservative and invasive approaches (needling
20 techniques).
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28 Conservative therapies are generally accepted as the first line of approach for managing
29 PT(6, 7), considering exercise as the gold standard of treatment, either eccentric exercise
30 (EE) or high slow resistance training programs. Both have demonstrated similar
31 effectiveness in the treatment of PT(6-8). In 2012, EE was shown to be effective in the
32 treatment of tendinopathies at various locations of the body, including PT, with a greater
33 likelihood of clinical improvement when performed on a declined surface(6, 8, 9). In
34 recent years, further evidence now supports the fact that exercise is more effective than
35 other conventional treatments in tendinopathy, such as iontophoresis, US, Cyriax
36 treatment, etc.(10).
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49 Physical therapy approaches for PT continue to evolve and a number of innovative
50 treatment options are now available, such as dry needling (DN)(11), electrotherapeutic
51 invasive modalities (e.g. electrolysis)(12-14) and extracorporeal shockwave (ECSW)
52 therapy(15). Recently, research has focused on regenerative therapies with high
53 expectations of success because some of these techniques seem to achieve a rapid
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3 regeneration of the injured tendon(11, 12, 16). However, evidence-based regenerative
4 therapies are limited and there is no agreement to date regarding which of these is the
5 most effective(17). DN consists of the insertion of a needle (filiform and solid, non-
6 beveled) with the aim of provoking a local injury leading to an inflammatory response
7 and the subsequent regeneration of the injured area in approximately one week. A study
8 performed by Abat et al. reported that DN induced histological and mechanical changes
9 in rat Achilles tendons at week one, with changes persisting at week four(18).
10 Percutaneous Needle Electrolysis (PNE) is an ultrasound-guided technique used by
11 physiotherapists consisting of causing localized lysis in the damaged and/or degenerated
12 tissue by means of a galvanic current transmitted through an acupuncture needle. This
13 technique may affect inflammatory mediators in damaged muscle tissue and influence the
14 new vascularization of the injured area in rats(18). James et al.(11) carried out a cohort
15 study in humans analyzing one group treated with DN and another treated with autologous
16 blood injections. In both cases, they found improvements compared to the baseline
17 measurements. However, this study failed to find differences between the different
18 treatments, concluding that both techniques were equally effective. In relation to PNE, a
19 former study(14) analyzed the treatment effect of electrolysis applied once a week in a
20 group of patients without any control or comparative group, reporting that patients
21 obtained statistically and clinically significant improvements compared to baseline
22 measurements.

23
24 From a biological point of view, it seems reasonable to hypothesize that a patient will
25 obtain benefits thanks to the mechanical effects provided by the needle(16), and that
26 patients may benefit more if the electrolysis effect is added to the mechanical stimuli
27 provided by the needle(19).
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3 Therefore, the aim of this study is to determine the additional effect of two interventions
4 combined with EE and compare which one is the most effective at short and long-term
5 follow-up for patients with PT.
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11 **METHODS AND ANALYSIS**

12 **Study design**

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15 The trial is designed as a randomized, controlled, participant, investigator and outcomes
16 assessor blinded, experimental study, aimed at comparing three different physiotherapy
17 protocols applied in three intervention groups of PT patients. Randomization will be
18 performed as block randomization with a 1:1:1 allocation.
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26 This protocol follows the standards of the Helsinki Convention of good clinical practices.
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28 The Ethics Committee of Aragon (CEICA) has evaluated the project and has given its
29 favorable opinion and support, N° PI15/0017 (Appendix 1).
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33 The study has been carried out following the SPIRIT statement for clinical trial protocol
34 and a SPIRIT Checklist has been included (Appendix 2).
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40 **Study setting**

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42 After reviewing the literature and observing the high incidence of this pathology in
43 amateur young adult athletes who perform sports and more specifically, jump sports,
44 patient recruitment has been performed in basketball, football, volleyball, CrossFit, and
45 handball sports clubs, together with running clubs and several gyms located in the city. A
46 decision was made to conduct the study in X, where the university is located, as well as
47 the laboratory to be used for assessments and treatments.
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54 The assessments will be conducted at the Motion Analysis laboratory of X, and the
55 treatment will be performed at two different sites depending on the availability of both
56 spaces and of schedules. Nonetheless, the same material will always be used.
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Participants

Inclusion criteria

Participants eligible for inclusion in this study must meet the following criteria: 1. History of PT and anterior knee pain located on the inferior pole of the patella for over three months; 2. Aged between 18 and 45 years; 3. Palpation tenderness of the superior insertion of the patellar tendon; 4. A score below 80 on the VISA-p questionnaire.

Exclusion criteria

Exclusion criteria for the study are: 1. Knee surgery within the previous six months; 2. Chronic joint diseases; 3. Corticosteroid injection in the patellar tendon within the previous three months; 4. Contraindications for needling; 5. Use of drugs 48 hours previously (e.g. NSAIDs); 6. Any other concomitant treatment for PT.

Methodology

In the first session, all participants will be instructed on how to perform a daily home program of EE. This will consist of performing three sets of 15 single leg squat repetitions on a decline board every day, according to Alfredson's protocol(20) increasing the speed if participants do not have pain. Participants will be informed that exercise is allowed to reach 5 in a numerical pain rating scale(21), and if it is higher then they will stop and notify the researcher, attempting once again 24 h later following the same rules.

For the interventions, the participants will be placed in a supine position with a pillow under the knee (approximately 20° of knee flexion). The area will be cleansed with an antiseptic solution (70% Propan-2-ol, Skin-des). An ultrasound probe cover will be used during the intervention for infectious control. To determine the relevant treatment area, two factors will be considered: 1) Palpation of the areas exhibiting higher sensitivity and

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3 that reproduce the patient's symptoms; 2) Tendon areas showing degenerative changes
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5 assessed under ultrasound. Each group will receive a total of four sessions distributed
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7 throughout eight weeks of treatment, once every two weeks.
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12 *DN intervention combined with EE (DN-G) and PNE intervention combined with EE*
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14 *(PNE-G)*

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16 Specific DN needles will be used during needling treatments, (Agu-punt, Spain).
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18 Considering the thickness of the tendon and the approach, we shall use needles measuring
19
20 0.25 x 25 mm. The procedure will be guided by US to ensure the specificity of application
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22 on the injured area and to guarantee that the procedure is safe for the patient. The DN
23
24 needle will reach the relevant treatment area (areas with degenerative PT changes). Each
25
26 session will consist of three needle insertions lasting three seconds each. In PNE-G
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28 applications, an intensity of 3 mA galvanic current will be used during the three seconds
29
30 that the procedure lasts(19). The dose of 3 mA has demonstrated to be as effective as 6
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32 mA in the treatment of tendinopathy injuries in animal models(18,19). In humans, a study
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34 conducted in 2016 showed that a dose of 3 mA in PT generated structural changes
35
36 compatible with tendon regeneration, together with improvement of functionality and
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38 pain (22). In contrast, the same study found that lower doses were effective only for the
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40 improvement of functionality and pain. As a result, a 3 mA dose was selected for this
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42 study.
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51 *Control group (CG)*

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53 A sham needle will be placed upon the treatment zone, simulating the same procedure as
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55 the rest of participants enrolled in the other groups. The needle will be placed in a specific
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57 holder and will be manipulated during the intervention to simulate a real treatment. This
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holder will have a cover over the bottom part of the same in order to avoid the needle contacting the skin.

Outcomes

Baseline data

Baseline data will include gender, age, height, weight, body-mass index, affected side, level, sports and frequency of physical activity, duration of symptoms, medication and previous rehabilitation treatments and infiltrations received. A blinded observer will assess all participants at baseline, 10 weeks and 22 weeks after baseline. Participants will be asked to inform the researchers if there were any changes in medication or if they are receiving any other treatment or infiltration during the study.

Primary outcome measure

Participants will complete the VISA-p questionnaire at baseline. The VISA-p questionnaire is designed to measure the severity of PT(23). The VISA-p score is the primary outcome variable. This scale consists of eight questions, the first six questions of which employ an analogical visual scale in order to assign a score of 0 to 10, where 10 represents the optimum state, for the purpose of quantifying pain and function in different activities, whereas the last two questions assess the level of functionality and ability to perform physical activity.

Secondary outcome measure

During the first evaluation, participants will complete the Visual Analog Scale (VAS), considering the level of pain they feel while practicing their sport's activity. Participants will be explained that a score of 0 indicates the absence of pain whereas a score of 10 represents the maximum tolerable pain. They will also complete a questionnaire to assess their quality of life (SF-36)(24).

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3 In order to assess tendon structure, an US evaluation using ultrasound equipment (Logic
4 S7 Expert, General Electric Healthcare) and a linear probe (MLG-15 5–10 MHz) will be
5 used. The ultrasonographic assessment protocol will be carried out according to the
6 Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European
7 Society of Musculoskeletal Radiology(25). The ultrasonographic assessment will consist
8 of a longitudinal sequence from the tendon origin to the insertion and transverse sections
9 on the pole of the patella, the tendon body and its insertion on the tibial tuberosity, with
10 the subject in supine position, with 20° knee flexion, and a pillow under the knee. The
11 presence of degenerative signs compatible with the medical diagnosis of PT (thickness of
12 the tendon, hypoechoic areas, irregularities affecting the cortical bone, calcifications) that
13 could be relevant for the selection of the target area will also be assessed. In addition,
14 CD-US assessment will be carried out to detect the presence of hypervascularization, with
15 the subject in supine position and with the knee relaxed in full extension, in order to obtain
16 further information to specifically define the target area.
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35 Upon completion of the evaluation, a jump test will be carried out, measured with a force
36 platform (FP4060-10-2000, Bertec Corporation). In this evaluation, subjects will warm
37 up during 5 minutes on a treadmill, subsequently, they will perform dynamic stretches for
38 the leg muscles. The Jump test will be explained to participants and they will be asked to
39 demonstrate how they will perform the assessment to ensure that they have understood it
40 before going to the platform. Later, patients will go to the platform forces and will
41 perform each jump 3 times (squat jump, Abalakov jump and countermovement jump test)
42 with 60 seconds between jumps and 2 minutes between different jumps (Table 1)(26-28).
43 The maximum height of the jump will be analyzed via the measurement of the flight time
44 recorded on the force platforms, the eccentric power and the maximum concentric force
45 performed. The Abalakov jump will be performed with the subject standing in an upright
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3 position with a full arm swing. A rapid downward movement will be immediately
4 followed by a rapid upward vertical movement as high as possible, all in one sequence.
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6 The same procedure will be applied for the CMJ jump, however, this test will be
7 performed with the hands on the hips to avoid arm swings. Finally, a Squat Jump will be
8 performed with 90 degrees of flexion of the knee.
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17 **Participant timeline**

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19 The study design will be a double-blind randomized controlled trial. The flow chart of
20 the trial is shown in Figure 1 and the check list SPIRIT schedule is shown in Figure 2.
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26 **'Patient and Public Involvement'**

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28 Patients with PT were not involved in setting the research question or the outcome
29 measures, however the concept of patient involvement translated to the execution phases
30 of the research. Patients and their families were central to the dissemination of the
31 information, which helped to recruit study participants. We intend to disseminate the main
32 results to trial participants and will seek patient and public involvement in the
33 development of an appropriate method of dissemination.
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45 **Sample size**

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47 Regarding the sample size, a calculation of statistical power was made prior to the study.
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49 Accepting an alpha risk of 0.05 and a beta risk in a bilateral contrast, 19 subjects are
50 needed in every treatment group to detect a difference equal or superior to 15 points on
51 the VISA-p scale and assuming a standard deviation of 15 points(29). The estimated rate
52 of loss to follow-up is 20%.
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3 Recruitment of subjects for the trial will take place between October 2018 and March
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5 2020 and will be carried out by means of informative campaigns targeted at different
6
7 Sports Clubs and Federations by means of e-mail and advertisements in the different
8
9 University mass media.

10
11
12 The interested subjects will receive an e-mail explaining the inclusion and exclusion
13
14 criteria, as well as the purpose of the study. If they meet the defined criteria, they will be
15
16 invited to send us their medical diagnosis.
17
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19
20

21 **Recruitment**

22
23 Participants will be recruited from sports clubs by the physiotherapist or the coach.
24
25 Contact has been made with various orthopedists who will collaborate with recruitment,
26
27 so that when they establish a diagnosis of this pathology in their examination room they
28
29 can refer us to the patients for their recruitment to the study.
30
31
32
33
34

35 **Allocation**

36
37 Participants will be randomly assigned to either CG or DN-G or PNE-G with a 1:1:1
38
39 allocation using an opaque envelope, with a block size of fifteen participants (5 for each
40
41 group).
42
43

44 Sealed opaque randomization envelopes with a study-specific participant number will be
45
46 supplied by an external statistician. A colleague not involved in the research study will
47
48 take the sealed opaque numbered envelopes in order, by number, and deliver the correct
49
50 envelope to the treating physical therapist. The envelope will contain a piece of paper,
51
52 which will be labelled with the same participant specific number, plus the group
53
54 assignment (PNE-G, DN-G or CG).
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1
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3 Participants who fulfill the inclusion criteria will receive the standardized oral and written
4 information, and, once they grant their consent to take part in the trial, they will be
5
6 randomized into the three groups.
7
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9

10 11 12 **Blinding**

13
14 Assessments regarding clinical recovery will be conducted by an assessor blinded to
15 treatment allocation. Due to the nature of the intervention, participants can be blinded to
16 allocation. Patients will be explained that they are going to receive a needling treatment,
17 that it may be slightly painful, and that if at any time they are unable to tolerate the pain
18 they must inform the researcher to stop the intervention. In order to blind patients, all the
19 interventions were made with the ultrasound and the PNE device connected to simulate
20 the same intervention in all groups. In contrast, the physiotherapist performing the
21 intervention cannot be blinded, however he/she will be instructed not to disclose the
22 allocation status of the participant at any time or during the follow up assessments. An
23 employee outside the research team will feed data into the computer in separate datasheets
24 so that the researchers can analyze data without having access to information about the
25 allocation.
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42 With the intention of evaluating patient blinding, an online questionnaire will be sent to
43 participants upon completion of the study, asking them about the treatment they received.
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49 **Data collection methods**

50
51 For the data collection, an oral questionnaire will be used containing questions targeted
52 at collecting baseline data and information concerning the pathology.
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1
2
3 Different questionnaires and assessment scales (VISA-p, VAS, SF-36) in Spanish will
4
5 be given to each participant in paper when they attend the assessment, and they will be
6
7 granted sufficient time to complete the same.
8
9

12 **Data management and statistical analysis**

14 In this study, all data will be entered electronically in the assessment room.

16 Original scales and questionnaires will be entered and kept on a locked file at the
17
18 participating site.
19

21 Participant files are to be stored in numerical order and stored in a secure and accessible
22
23 place and manner. Participant files will be maintained in storage for a period of 2 years
24
25 after completion of the study.
26

28 The statistical analysis will be carried out by an intention-to-treat analysis. Variables will
29
30 be described in number (percentage) and average (standard deviation) or median
31
32 (interquartile range) attending to their distribution. Quantitative variables will be
33
34 analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine
35
36 correct statistical tests according to these results.
37
38

39 Outcomes will be analyzed using mixed linear and logistic regression models considering
40
41 participants as a random effect and group of treatment as fixed factors. Baseline
42
43 characteristics will be introduced in the model as covariance. Numbers needed to treat
44
45 index will also be calculated. The primary aim of the analysis will be to calculate the
46
47 difference obtained in the VISA-p score after the intervention (final measurement - initial
48
49 measurement). Finally, the magnitude of the effect of the result will be calculated and
50
51 therefore its clinical importance, by means of the following formula:
52
53

$$54 \quad I^* = \sqrt{\frac{F(1,dfR)}{F(1,dfR) + dfR}}$$

56 The significance level set for all the analysis will be $p \leq 0.05$.
57
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ETHICS AND DISEMINATION

The study design, procedures and informed consent procedure were approved and consequently the study will be carried out in compliance with the Helsinki Declaration of Human Rights. All participants will have to provide written Spanish informed consent.

Appendix 1.

The results for this trial will be published in peer-reviewed international journals or otherwise made publicly available and will be presented at national and international conferences and symposiums irrespective of the outcomes.

Any modifications to the protocol, which may impact the study procedures, potential patient benefits or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be approved by the Ethics Committee prior to implementation and notified to the health authorities in accordance with local regulations.

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored identified by code number. All local databases will be secured with password-protected access systems.

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

DISCUSSION

1
2
3 This study seeks to investigate the effects of physiotherapy needling techniques on pain,
4
5 functionality and quality of life in PT.
6

7
8 PT is a common cause of knee pain in cases of degeneration of the patellar tendon. Among
9
10 the causes of PT, extrinsic factors (e.g., patellar tendon loading with exercise) and
11
12 intrinsic factors (e.g., malalignment, high patella, imbalances) have been proposed(30).
13
14 Traditionally, the focus has been on quadriceps strengthening exercises and many reviews
15
16 have shown that the effect of the treatment could be estimated to give the patients a 50-
17
18 70% change of improvement on pain and functionality(6, 31, 32).
19

20
21 Regarding needling treatment, previous studies have shown a great improvement in PT
22
23 using PNE in combination with EE, with all patients reporting an improvement at least
24
25 one month after treatment(12-14, 18). This is an improvement compared to the minimum
26
27 three months needed to improve symptoms by applying other conventional techniques
28
29 (pharmacological and biological treatments, cold/heat techniques, shock waves, etc.)
30
31 Additionally, in a long-term study conducted in 2013, this technique was shown to
32
33 improve symptoms quickly and steadily for at least 10 years(33). These findings
34
35 demonstrate that this technique ensures that patients remain pain-free for a long period.
36
37 Furthermore, we were only able to find four articles(12-14, 18) addressing the application
38
39 of PNE for the recovery of PT, however, none of the articles studied were RCTs, which
40
41 entail limited evidence of the effectiveness of this technique.
42
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45

46
47 In addition, there are no standardized protocols for the application of PNE, which explains
48
49 the great variability in the number of sessions and application time based on the literature.
50
51 Therefore, this study aims to facilitate clinical practice and combine the available
52
53 methodology criteria in the application of this promising technique.
54

55
56 Regarding DN, the literature shows many similarities with PNE, since there is only one
57
58 RCT that compares functionality improvements among patients who have received PRP.
59
60

1
2
3 This study reflected that in the short term PRP had better results for pain and functionality,
4
5 however, DN was more effective than PRP after six months(34).
6

7
8 For the application of both needling techniques, US-guidance is normally used to be able
9
10 to observe firstly the presentation of the tendon, and later to observe the needle and enable
11
12 a much more specific treatment approach. However, US has disadvantages including its
13
14 operator dependence and the limited ability to rule out intra-articular disease. The
15
16 sensitivity and specificity of ultrasonography for patellar tendinopathy is between 58%
17
18 and 94%, respectively(35).
19

20
21 Moreover, functionality of the tendon is usually measured with the VISA-p(36,37),
22
23 whereas jump tests (representing a similar action to that performed in subject's daily
24
25 sports) are only evaluated in a few papers(27,38). Countermovement jumps and squat
26
27 jumps are the most reliable and valid field tests for the estimation of the explosive power
28
29 of the lower limbs in physically active men(39). Thus, we will combine both, in order to
30
31 be more accurate in the assessment of the tendon's functionality, and be able to assess
32
33 changes that may affect their sport performance.
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37 This study has several strengths. First, we will evaluate two techniques that currently lack
38
39 strong evidence. However, in doing so, we are contributing to new knowledge in the field
40
41 of the recovery of musculoskeletal injuries. Second, the role of invasive techniques will
42
43 be determined by comparing the effects between these techniques and a control group.
44
45 The reliability of data is ensured, as both patients and the assessor will be blinded. Third,
46
47 a sub-analysis with US will be performed to investigate changes in the presence of
48
49 calcifications, cortical irregularities, neovascularization, thickness, eco-intensity, eco-
50
51 variation and eco-texture of the patellar tendon.
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3 However, there are some limitations to this study. Blinding of the physiotherapist
4 performing the intervention is not possible. Furthermore, follow-up is limited to 22 weeks
5 after baseline.
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10 The findings obtained may help advance the treatment of this injury by identifying the
11 most effective treatment protocol and to avoid the associated consequences, such as the
12 prevention of relapses and reducing the potential impact on the musculoskeletal system.
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10 **AUTHOR'S CONTRIBUTIONS**

11 MPL, EMG and PH conceived of the idea, and developed the intervention. MPL and PH
12 wrote the article. MPL, MO, RMG, AVB, ZA, YH and PH developed the design of the
13 trial. MO were involved in development of the statistical analysis of the trial and
14 contributed to the content of the article. AVB contributed to the design and writing of the
15 jump test protocol. All authors have read and approved the final manuscript.
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28 **FUNDING STATEMENT**

29 This research received no specific grant from any funding agency in the public,
30 commercial or not-for-profit sectors.
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36 **COMPETING INTEREST STATEMENT**

37 The authors declare that they have no competing interests.
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TABLES

Table 1. Jump test's protocol.

JUMP TEST PROTOCOL	
5-minute warm-up consisting of steady jogging on a treadmill	
Dynamic Stretches lasting 5 minutes, as instructed by the physical therapist	Psoas Quadriceps Gluteus maximus Gastrocnemius Hamstring muscles
Three jump tests are performed - 3 jumps off the ground for 3 times for the patient to become familiar with the tests - The subject is placed on the platform and asked to perform each test 3 times, with 60 seconds rest between the different tests	Abalakov test Countermovement jump test Squat jump
The highest jump is selected for the study	

FIGURES

Figure 1. Flow diagram. Randomized controlled trial design.

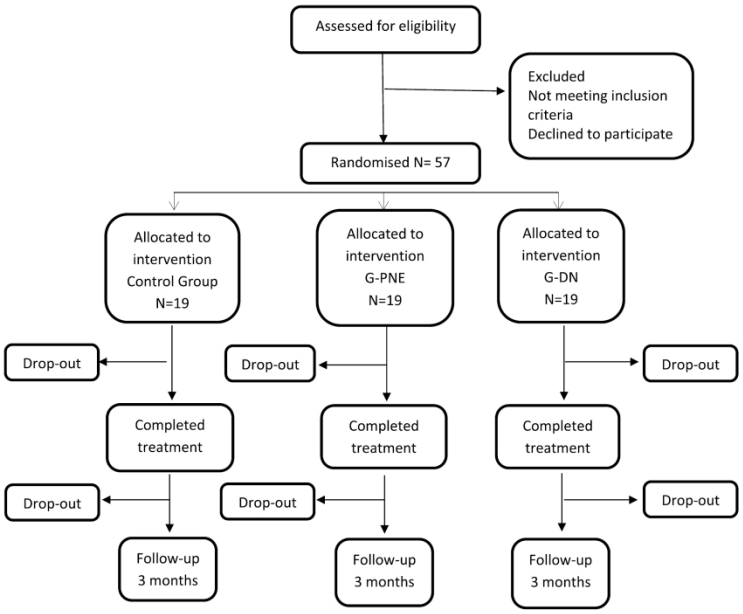
G-PNE: Percutaneous Needle Electrolysis Group. G-DN: Dry Needle Group.

Figure 2. Schedule for the enrolment and intervention.

Schedule for enrolment and intervention per cluster. -t1: baseline; t1-t2: intervention period; t2: 8 weeks after baseline; t3: 10 weeks after baseline; t4: 3 months after baseline. G-PNE: Percutaneous Needle Electrolysis Group; G-DN: Dry Needle Group; US: ultrasound.

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Figure 1. Flow diagram. Randomized controlled trial design.



210x297mm (300 x 300 DPI)

Figure 2. Schedule for enrolment and intervention.

	Enrolment	Allocation	Close-out			
TIMEPOINT**	-t ₁	0	t ₁	t ₂	t ₃	t ₄
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
<i>Control group</i>			↔			
<i>G-PNE</i>			↔			
<i>G-DN</i>			↔			
ASSESSMENTS:						
<i>Baseline demographic information</i>	X					
<i>VISA-P</i>	X		X		X	X
<i>VAS</i>			X		X	X
<i>SF-36</i>			X		X	X
<i>Tendon structure US</i>			X		X	X
<i>Jump test</i>			X		X	X

215x279mm (300 x 300 DPI)

DOCUMENTO DE INFORMACIÓN AL PACIENTE

Fecha:

Título del proyecto: “ESTUDIO COMPARATIVO ENTRE TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Investigador principal:

Doña: M^a Pilar López Royo

Este estudio se basa en el estudio comparativo de tratamientos que utilizan distintas técnicas de fisioterapia invasiva junto con un programa de ejercicio excéntrico para el tratamiento de la tendinopatía rotuliana. Por medio del tratamiento se produce una disminución del dolor asociado a esta patología y un aumento de la fuerza de la pierna, lo que a su vez hace que mejore la funcionalidad en las actividades de la vida diaria y mejore la calidad de vida.

PROCESO DE SELECCIÓN DE PACIENTES

Criterios de inclusión:

- Edad comprendida entre 18 y 40 años.
- Practicar cualquier deporte de forma habitual.
- Pacientes con diagnóstico médico de tendinopatía rotuliana crónica con un mínimo de 3 meses de evolución y con sintomatología.
- Dolor a la palpación del tendón en el polo inferior de la rótula y durante el entrenamiento o competición.
- Puntuación del cuestionario VISA-P menor de 80 (el resultado obtenido de rellenar el cuestionario tiene que ser menor de 80 puntos de los 100 posibles para poder participar en el estudio).

Criterios de exclusión:

- Paciente operado de la rodilla afectada en los últimos 6 meses.
- Infiltraciones en la rodilla afectada en los últimos 3 meses.
- Paciente que ha recibido tratamiento farmacológico o fisioterápico en las últimas 48 horas o durante el estudio.
- Patología con menos de 3 meses de evolución.
- Presentar tendinopatía rotuliana bilateral.
- Puntuación del cuestionario VISA-p mayor o igual de 80 (el resultado obtenido de rellenar el cuestionario no puede ser igual o superar los 80 puntos de los 100 posibles, sino no podrá participar en el estudio).
- Imposibilidad para aplicar alguna de las técnicas de tratamiento o valoración por

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2 contraindicación absoluta o relativa.
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7 **PROCEDIMIENTO**

8 El tratamiento consiste en realizar un protocolo de ejercicios excéntricos de cuádriceps que
9 realizará en casa de forma diaria, y que serán revisados con el fisioterapeuta para valorar su
10 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
11 según el protocolo de tratamiento propuesto de forma totalmente **aleatorizada** y según los
12 criterios diagnósticos específicos de la misma, siguiendo las indicaciones, criterios de aplicación y
13 criterios diagnósticos.
14

15 Son técnicas de punción cuyo objetivo es producir una respuesta inflamatoria aguda que active los
16 mecanismos fisiológicos de regeneración del tejido y mejorar el dolor y la funcionalidad en la
17 articulación de la rodilla, se realiza con agujas de punción seca, similares a las agujas de
18 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
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25 Los registros serán realizados en el Espacio de Valoración Funcional de la Universidad San Jorge,
26 en la Facultad de Ciencias de la Salud, Edificio III. Se pondrá a su disposición la posibilidad de
27 utilizar el autobús que utiliza el personal y alumnado de la universidad (en el horario que éste esté
28 disponible). Las fechas y horarios serán convenidas con cada participante en función de su
29 disponibilidad y la de los investigadores, buscando la conformidad de todos. La duración
30 aproximada del estudio para cada paciente será de 30 minutos, aunque este horario podrá variar
31 en función de los acontecimientos.
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38 Será recibido por los miembros del equipo de investigación y una vez allí, se le realizará un primer
39 análisis fisioterápico, rellenará una encuesta, una escala analógica visual (EVA) del dolor y el
40 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.
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42

43 Tras éste primer registro se le colocará un marcador pasivo en el pantalón. Se le pedirá que
44 realice el siguiente protocolo:
45

- 46 - Calentamiento de 5 minutos en cinta a ritmo constante.
- 47 - Estiramientos dinámicos de psoas, cuádriceps, glúteo, gastrocnemios, isquiotibiales durante 5
- 48 minutos instruidos por el fisioterapeuta.
- 49 - Realización de los 3 saltos fuera de la plataforma durante 3 veces para que se familiarice con los
- 50 tests.
- 51 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 52 con contramovimiento (CMJ) y el squatjump (SJ).
- 53
- 54 Se colocará en la plataforma y realizará 3 saltos de cada uno de los test con una separación entre
- 55 ellos de 60 segundos.
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Se valora el tendón por ecografía, y se recogen datos por medio de personal adiestrado y se envía

1 a personal especialista en radiodiagnóstico.

2
3 Tras los registros de los saltos se dará por finalizada la valoración.

4
5
6 Tras la 1ª valoración, se realizará una división en tres grupos de los pacientes de forma
7 aleatorizada.

8
9 Se le realizará el protocolo de tratamiento de fisioterapia invasiva que le haya correspondido.
10 Realizará una sesión del tratamiento cada 14 días, y se realizará la 2ª valoración 1 semana más
11 tarde de la 4ª sesión de punción para valorar los cambios que se hayan producido tras el
12 tratamiento, repitiéndose de nuevo el proceso de recogida de datos realizado al inicio del estudio.
13 Se realizará un seguimiento a los tres meses de la valoración post-tratamiento para valorar la
14 eficacia de la técnica a largo plazo del tratamiento.

15
16 El procedimiento se realizará guiado ecográficamente para asegurar la especificidad de aplicación
17 sobre la zona relevante de tratamiento y garantizar la seguridad de la técnica. Se hace posterior a
18 esta intervención una serie de ejercicios excéntricos de cuádriceps. El tratamiento se realizará
19 durante 4 sesiones (a razón de una sesión cada 14 días).

26 **RIESGOS**

27 La aplicación de las técnicas de punción utilizadas no han demostrado tener ningún efecto
28 secundario hasta la fecha, aunque el paciente puede experimentar dolor durante y tras la punción,
29 generalmente de uno o dos días de duración.

34 **RESPONSABILIDADES DEL PARTICIPANTE**

35 La información que usted posea sobre su estado de salud o sobre sensaciones previas
36 anormales al realizarle una punción, puede afectar la seguridad o el valor de estas pruebas. La
37 rápida comunicación por su parte de las sensaciones que experimenta al realizar esta prueba es
38 también de gran importancia. Usted es responsable de revelar esa información al personal de la
39 prueba cuando se le pregunte.

45 **PREGUNTAS**

46 Le animamos a que haga cualquier pregunta sobre los procedimientos seguidos o sus resultados
47 en la prueba. Si tiene alguna preocupación o pregunta, por favor pídasenos más información, para
48 ello le dejamos un correo electrónico mapilr86@hotmail.com y un número de teléfono móvil:
49 616102365.

54 **LIBERTAD PARA DAR EL CONSENTIMIENTO**

55 Usted participa en el estudio de manera voluntaria, pudiendo abandonarlo en el momento
56 que considere oportuno, sin que esto conlleve ninguna repercusión negativa para usted.

57 Los datos obtenidos en el estudio serán confidenciales y únicamente se hará uso de ellos

1
2 para el cumplimiento de los objetivos planteados en la investigación. No se cederán estos datos a
3 terceros sin el consentimiento expreso de los sujetos participantes a quienes pertenezcan los
4 datos.
5

6 En esta investigación se garantizará el anonimato de los sujetos que aportan los datos,
7 estableciendo un código disociado para identificarlos que sólo será conocido por los responsables
8 de la realización del trabajo de campo.
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17 Fdo: M^a Pilar López Royo
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MODELO DE CONSENTIMIENTO INFORMADO

Título del PROYECTO: “ESTUDIO COMPARATIVO ENTRE TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Doña: M^a Pilar López Royo (mapilr86@hotmail.com)
Departamento de Fisiatría y Enfermería
UNIVERSIDAD DE ZARAGOZA

Yo, (nombre y apellidos del participante)

He recibido suficiente información en relación con el proyecto, he leído la hoja de información que se me ha entregado y he podido hacer preguntas sobre el proyecto, recibiendo respuestas satisfactorias.

Entiendo que la participación es voluntaria y que puedo abandonar el proyecto:

- . Cuando lo desee
- . Sin tener que dar explicaciones
- . Sin que esto repercuta en mis cuidados médicos

He sido claramente informado de forma clara y precisa del tratado que recibirán mis datos personales que se contienen en este proyecto, sabiendo que los datos serán tratados y custodiados bajo mi intimidad y a la vigente normativa de la protección de datos, y que sobre estos datos me asisten los derechos de rectificación, acceso y oposición comunicándolo al investigador principal que figura en este consentimiento.

Declaro que presto libremente mi conformidad para participar en el estudio.

Deseo ser informado sobre los resultados del estudio: sí no (marque lo que proceda)

Así pues, acepto que las muestras derivadas de este proyecto puedan ser utilizadas en futuras investigaciones siempre y cuando están relacionadas con ésta.

Por lo tanto, doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno al centro, para los fines del estudio, y soy consciente de que este consentimiento es

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2 revocable.
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7 Firma del participante:

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10 Fecha:

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17 He explicado la naturaleza y el propósito del proyecto al paciente mencionado
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21 Firma del Investigador:

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24 Fecha:

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31 Consentimiento informado estudio _____
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33 Versión _____, fecha _____
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3 **Appendix 2. Checklist SPIRIT**
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6 SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and
7 related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1-3
	2b	All items from the World Health Organization Trial Registration Data Set	2-3
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	22
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5-6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13

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4	Implemen	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
5	tation			
6	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial	13
7	(masking)		participants, care providers, outcome assessors, data analysts), and	
8			how	
9		17b	If blinded, circumstances under which unblinding is permissible, and	13
10			procedure for revealing a participant's allocated intervention during the	
11			trial	
12				
13	Methods: Data collection, management, and analysis			
14				
15	Data	18a	Plans for assessment and collection of outcome, baseline, and other	13-14
16	collection		trial data, including any related processes to promote data quality (eg,	
17	methods		duplicate measurements, training of assessors) and a description of	
18			study instruments (eg, questionnaires, laboratory tests) along with their	
19			reliability and validity, if known. Reference to where data collection	
20			forms can be found, if not in the protocol	
21		18b	Plans to promote participant retention and complete follow-up,	N/A
22			including list of any outcome data to be collected for participants who	
23			discontinue or deviate from intervention protocols	
24				
25	Data	19	Plans for data entry, coding, security, and storage, including any	14
26	management		related processes to promote data quality (eg, double data entry; range	
27			checks for data values). Reference to where details of data	
28			management procedures can be found, if not in the protocol	
29				
30	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.	14
31	methods		Reference to where other details of the statistical analysis plan can be	
32			found, if not in the protocol	
33		20b	Methods for any additional analyses (eg, subgroup and adjusted	14
34			analyses)	
35				
36		20c	Definition of analysis population relating to protocol non-adherence (eg,	14
37			as randomised analysis), and any statistical methods to handle missing	
38			data (eg, multiple imputation)	
39				
40	Methods: Monitoring			
41				
42	Data	21a	Composition of data monitoring committee (DMC); summary of its role	-
43	monitoring		and reporting structure; statement of whether it is independent from the	
44			sponsor and competing interests; and reference to where further	
45			details about its charter can be found, if not in the protocol.	
46			Alternatively, an explanation of why a DMC is not needed	
47		21b	Description of any interim analyses and stopping guidelines, including	-
48			who will have access to these interim results and make the final	
49			decision to terminate the trial	
50				
51	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and	-
52			spontaneously reported adverse events and other unintended effects of	
53			trial interventions or trial conduct	
54				
55	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and	N/A
56			whether the process will be independent from investigators and the	
57			sponsor	
58	Ethics and dissemination			
59				
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Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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BMJ Open

A comparative study of treatment interventions for patellar tendinopathy: a protocol for a randomized controlled trial

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Complete List of Authors:	Lopez-Royo, Maria Pilar; Universidad San Jorge Facultad de Ciencias de la Salud; Universidad de Zaragoza, Facultad de Ciencias de la Salud y del Deporte Gómez-Trullén, Eva Maria; Universidad de Zaragoza, Facultad de Ciencias de la Salud y del Deporte Ortiz-Lucas, Maria; Universidad San Jorge Facultad de Ciencias de la Salud Galán-Díaz, Rita Maria; Universidad San Jorge Facultad de Ciencias de la Salud Bataller-Cervero, Ana Vanessa; Universidad San Jorge Facultad de Ciencias de la Salud Al-Boloushi, Zaid; Universidad de Zaragoza Facultad de Ciencias, Facultad de Ciencias de la Salud y del Deporte; Kuwait Ministry of Health Hamam-Alcober, Yasmina; Universidad San Jorge Facultad de Ciencias de la Salud, Fisioterapia Herrero, Pablo; Universidad San Jorge Facultad de Ciencias de la Salud
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine, Pathology
Keywords:	Eccentric Exercise, Tendinopathy, Percutaneous Needle Electrolysis, Dry Needling

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3 A comparative study of treatment interventions for patellar tendinopathy: a protocol for
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5 a randomized controlled trial
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8 López-Royo MP^{a,b}, Gómez-Trullén EM^b, Ortiz-Lucas M^a, Galán-Díaz RM^a, Bataller-Cervero
9
10 AV^a, Al-Boloushi Z^{b,c}, Hamam-Alcober Y^a, Herrero P^{a*}
11
12

13 **AFFILIATIONS**
14

- 15
16 **A.** iPhysio Research Group. Universidad San Jorge. Campus Universitario, Autov.
17
18 A23 km 299, 50830. Villanueva de Gállego, Zaragoza, Spain.
19
20 **B.** Universidad de Zaragoza. Facultad de Ciencias de la Salud y del Deporte. Dpto.
21
22 de Fisiatría y Enfermería. C/ Domingo Miral s/n, 50009 - Zaragoza, Spain.
23
24 **C.** Ministry of Health, State of Kuwait. Jamal Abdunnasser Street, Al Solaibeykhat
25
26 Area 5. Kuwait City. Safat 13001.
27
28
29
30
31
32

33 ***CORRESPONDENCE TO:**
34

35
36 Dr. Pablo Herrero. iPhysio Research Group. Universidad San Jorge. Campus
37
38 Universitario, Autov A23, Km 299, 50830 Villanueva de Gállego, Zaragoza, Spain.
39
40 Tel.: (+34) 976 060 100 Fax: 976 077 581. Email: pherrero@usj.es
41
42

43 **ADDITIONAL AUTHOR INFORMATION**
44

45
46 Maria Pilar López Royo. Emails: mplopez@usj.es
47
48

49
50 Eva María Gómez Trullén. Email: evagomez@unizar.es
51

52
53 María Ortiz Lucas. Email: mariaortizlucas@gmail.com
54

55
56 Rita María Galán Díaz. Email: rmgalan@usj.es
57

58
59 Ana Vanessa Bataller-Cervero. Email: avbataller@usj.es
60

1
2
3 Yasmina Hamam-Alcober. Email: yhamam@usj.es
4
5

6 Zaid AL-boloushi. Email: boloushi@me.com
7
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12 **WORD COUNT:** 3967 words.
13
14
15

16 17 **ABSTRACT**

18
19 **Introduction:** Patellar tendinopathy is a degenerative disease of the patellar tendon,
20 which affects athletes from a variety of sports, and is especially predominant in sports
21 involving high-impact jumping. The aim of this study is to determine the additional effect
22 of two interventions combined with eccentric exercise and compare which one is the most
23 effective at short and long-term follow-up for patients with patellar tendinopathy.
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31 **Methods and analysis:** This study is a randomized controlled trial with blinded
32 participants. Measurements will be carried out by a specially trained blinded assessor. A
33 sample of 57 patients with a medical diagnosis of patellar tendinopathy will participate
34 in this study and will be divided into three treatment groups. Eligible participants will be
35 randomly allocated to receive either: (a) treatment group with Percutaneous Needle
36 Electrolysis, (b) treatment group with Dry Needling or (c) treatment group with placebo
37 needling. In addition, all groups will perform eccentric exercise. Functionality and muscle
38 strength parameters, pain, ultrasound appearances and patient perceived quality of life
39 shall be evaluated using the VISA-p, jump test, VAS, US images and SF-36, respectively.
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Participants will be assessed at baseline, at 10 weeks and at 22 weeks after baseline. The
expected findings will allow us to advance in the treatment of this injury, as they will help
determine whether a needling intervention has additional effects on an eccentric exercise
program and whether any of the needling modalities is more effective than the other.

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3 **Ethics and dissemination:** This protocol has been approved by the Ethics Committee of
4 Aragon (N° PI15/0017). The trial will be conducted in accordance with the Declaration
5 of Helsinki.
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9 **Trial Registration Number:** NCT02498795.
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12 13 14 **Strengths and limitations of this study**

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17 - This randomized clinical trial will report the effects on functionality and pain of three
18 different treatment interventions in both the short and long term.
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21 - The double-blinded and placebo-control design will enhance objectivity and help reduce
22 bias.
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25 - The effects of two minimally invasive treatments in physical therapy will be compared
26 for the first time in patellar tendinopathy.
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33 **INTRODUCTION**

34
35 Patellar tendinopathy (PT), also known as jumper's knee, is a degenerative condition
36 affecting the patellar tendon resulting in anterior knee pain associated with focal and
37 palpable tenderness at the inferior pole of the patella. This disorder has similar histologic
38 findings to other tendon disorders characterized by an increased thickness of the tendon
39 and changes in vascularity, and cellularity, with incompletely healed tendon micro-
40 ruptures and disturbed collagen distribution(1).
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49 This degenerative condition affects athletes from a variety of sports, and is especially
50 predominant in sports involving high-impact jumping. The overall prevalence of PT in
51 non-elite players is 8.5%, although this figure increases in sports that place high demands
52 on the patellar ligament, increasing up to 14.2% in volleyball athletes. Among elite
53 volleyball and basketball players, a prevalence of 45% and 32%, respectively, has been
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3 reported. In addition, jumper's knee is almost twice as common among male non-elite
4 athletes when compared with female athletes(2).

7 The diagnosis is typically based on the clinical history and symptomatic findings.
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9
10 Currently, imaging techniques, such as color-Doppler ultrasound (CD-US) and gray scale
11
12 ultrasound (GS-US) can be used for the assessment of the patellar tendon to clinically
13
14 confirm the diagnosis(3).

16
17 Treatments used for PT fall into two major groups. The first group comprises medical
18
19 treatments which include non-steroidal anti-inflammatory drugs (NSAIDs), platelet-rich
20
21 plasma injection(4) and autologous growth factors(5). The second group consists of
22
23 physical therapies, including both conservative and invasive approaches (needling
24
25 techniques).

27
28 Conservative therapies are generally accepted as the first line of approach for managing
29
30 PT(6, 7), considering exercise as the gold standard of treatment, either eccentric exercise
31
32 (EE) or high slow resistance training programs. Both have demonstrated similar
33
34 effectiveness in the treatment of PT(6-8). In 2012, EE was shown to be effective in the
35
36 treatment of tendinopathies at various locations of the body, including PT, with a greater
37
38 likelihood of clinical improvement when performed on a declined surface(6, 8, 9). In
39
40 recent years, further evidence now supports the fact that exercise is more effective than
41
42 other conventional treatments in tendinopathy, such as iontophoresis, US, Cyriax
43
44 treatment, etc.(10).

47
48 Physical therapy approaches for PT continue to evolve and a number of innovative
49
50 treatment options are now available, such as dry needling (DN)(11), electrotherapeutic
51
52 invasive modalities (e.g. electrolysis)(12-14) and extracorporeal shockwave (ECSW)
53
54 therapy(15). Recently, research has focused on regenerative therapies with high
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56 expectations of success because some of these techniques seem to achieve a rapid
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3 regeneration of the injured tendon(11, 12, 16). However, evidence-based regenerative
4 therapies are limited and there is no agreement to date regarding which of these is the
5 most effective(17). DN consists of the insertion of a needle (filiform and solid, non-
6 beveled) with the aim of provoking a local injury leading to an inflammatory response
7 and the subsequent regeneration of the injured area in approximately one week. A study
8 performed by Abat et al. reported that DN induced histological and mechanical changes
9 in rat Achilles tendons at week one, with changes persisting at week four(18).
10 Percutaneous Needle Electrolysis (PNE) is an ultrasound-guided technique used by
11 physiotherapists consisting of causing localized lysis in the damaged and/or degenerated
12 tissue by means of a galvanic current transmitted through an acupuncture needle. This
13 technique may affect inflammatory mediators in damaged muscle tissue and influence the
14 new vascularization of the injured area in rats(18). James et al.(11) carried out a cohort
15 study in humans analyzing one group treated with DN and another treated with autologous
16 blood injections. In both cases, they found improvements compared to the baseline
17 measurements. However, this study failed to find differences between the different
18 treatments, concluding that both techniques were equally effective. In relation to PNE, a
19 former study(14) analyzed the treatment effect of electrolysis applied once a week in a
20 group of patients without any control or comparative group, reporting that patients
21 obtained statistically and clinically significant improvements compared to baseline
22 measurements.

23
24 From a biological point of view, it seems reasonable to hypothesize that a patient will
25 obtain benefits thanks to the mechanical effects provided by the needle(16), and that
26 patients may benefit more if the electrolysis effect is added to the mechanical stimuli
27 provided by the needle(19).
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3 Therefore, the aim of this study is to determine the additional effect of two interventions
4 combined with EE and compare which one is the most effective at short and long-term
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6 follow-up for patients with PT.
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11 **METHODS AND ANALYSIS**

12 **Study design**

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15 The trial is designed as a randomized, controlled, participant, investigator and outcomes
16 assessor blinded, experimental study, aimed at comparing three different physiotherapy
17 protocols applied in three intervention groups of PT patients. Randomization will be
18 performed as block randomization with a 1:1:1 allocation.
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26 This protocol follows the standards of the Helsinki Convention of good clinical practices.
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28 The Ethics Committee of Aragon (CEICA) has evaluated the project and has given its
29 favorable opinion and support, N° PI15/0017 (Appendix 1).
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33 The study has been carried out following the SPIRIT statement for clinical trial protocol
34 and a SPIRIT Checklist has been included (Appendix 2).
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39 **Study setting**

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41 After reviewing the literature and observing the high incidence of this pathology in
42 amateur young adult athletes who perform sports and more specifically, jump sports,
43 patient recruitment has been performed in basketball, football, volleyball, CrossFit, and
44 handball sports clubs, together with running clubs and several gyms located in the city. A
45 decision was made to conduct the study in X, where the university is located, as well as
46 the laboratory to be used for assessments and treatments.
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54 The assessments will be conducted at the Motion Analysis laboratory of X, and the
55 treatment will be performed at two different sites depending on the availability of both
56 spaces and of schedules. Nonetheless, the same material will always be used.
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Participants

Inclusion criteria

Participants eligible for inclusion in this study must meet the following criteria: 1. History of PT and anterior knee pain located on the inferior pole of the patella for over three months; 2. Aged between 18 and 45 years; 3. Palpation tenderness of the superior insertion of the patellar tendon; 4. A score below 80 on the VISA-p questionnaire.

Exclusion criteria

Exclusion criteria for the study are: 1. Knee surgery within the previous six months; 2. Chronic joint diseases; 3. Corticosteroid injection in the patellar tendon within the previous three months; 4. Contraindications for needling; 5. Use of drugs 48 hours previously (e.g. NSAIDs); 6. Any other concomitant treatment for PT.

Methodology

In the first session, all participants will be instructed on how to perform a daily home program of EE. This will consist of performing three sets of 15 single leg squat repetitions on a decline board every day, according to Alfredson's protocol(20) increasing the speed if participants do not have pain. Participants will be informed that exercise is allowed to reach 5 in a numerical pain rating scale(21), and if it is higher then they will stop and notify the researcher, attempting once again 24 h later following the same rules.

For the interventions, the participants will be placed in a supine position with a pillow under the knee (approximately 20° of knee flexion). The area will be cleansed with an antiseptic solution (70% Propan-2-ol, Skin-des). An ultrasound probe cover will be used during the intervention for infectious control. To determine the relevant treatment area, two factors will be considered: 1) Palpation of the areas exhibiting higher sensitivity and

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3 that reproduce the patient's symptoms; 2) Tendon areas showing degenerative changes
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5 assessed under ultrasound. Each group will receive a total of four sessions distributed
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7 throughout eight weeks of treatment, once every two weeks.
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12 *DN intervention combined with EE (DN-G) and PNE intervention combined with EE*
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14 *(PNE-G)*
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16 Specific DN needles will be used during needling treatments, (Agu-punt, Spain).
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18 Considering the thickness of the tendon and the approach, we shall use needles measuring
19
20 0.25 x 25 mm. The procedure will be guided by US to ensure the specificity of application
21
22 on the injured area and to guarantee that the procedure is safe for the patient. The DN
23
24 needle will reach the relevant treatment area (areas with degenerative PT changes). Each
25
26 session will consist of three needle insertions lasting three seconds each. In PNE-G
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28 applications, an intensity of 3 mA galvanic current will be used during the three seconds
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30 that the procedure lasts(19). The dose of 3 mA has demonstrated to be as effective as 6
31
32 mA in the treatment of tendinopathy injuries in animal models(18,19). In humans, a study
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34 conducted in 2016 showed that a dose of 3 mA in PT generated structural changes
35
36 compatible with tendon regeneration, together with improvement of functionality and
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38 pain (22). In contrast, the same study found that lower doses were effective only for the
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40 improvement of functionality and pain. As a result, a 3 mA dose was selected for this
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42 study.
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51 *Control group (CG)*
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53 A sham needle will be placed upon the treatment zone, simulating the same procedure as
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55 the rest of participants enrolled in the other groups. The needle will be placed in a specific
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57 holder and will be manipulated during the intervention to simulate a real treatment. This
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holder will have a cover over the bottom part of the same in order to avoid the needle contacting the skin.

Outcomes

Baseline data

Baseline data will include gender, age, height, weight, body-mass index, affected side, level, sports and frequency of physical activity, duration of symptoms, medication and previous rehabilitation treatments and infiltrations received. A blinded observer will assess all participants at baseline, 10 weeks and 22 weeks after baseline. Participants will be asked to inform the researchers if there were any changes in medication or if they are receiving any other treatment or infiltration during the study.

Primary outcome measure

Participants will complete the VISA-p questionnaire at baseline. The VISA-p questionnaire is designed to measure the severity of PT(23). The VISA-p score is the primary outcome variable. This scale consists of eight questions, the first six questions of which employ an analogical visual scale in order to assign a score of 0 to 10, where 10 represents the optimum state, for the purpose of quantifying pain and function in different activities, whereas the last two questions assess the level of functionality and ability to perform physical activity.

Secondary outcome measure

During the first evaluation, participants will complete the Visual Analog Scale (VAS), considering the level of pain they feel while practicing their sport's activity. Participants will be explained that a score of 0 indicates the absence of pain whereas a score of 10 represents the maximum tolerable pain. They will also complete a questionnaire to assess their quality of life (SF-36)(24).

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3 In order to assess tendon structure, an US evaluation using ultrasound equipment (Logic
4 S7 Expert, General Electric Healthcare) and a linear probe (MLG-15 5–10 MHz) will be
5 used. The ultrasonographic assessment protocol will be carried out according to the
6 Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European
7 Society of Musculoskeletal Radiology(25). The ultrasonographic assessment will consist
8 of a longitudinal sequence from the tendon origin to the insertion and transverse sections
9 on the pole of the patella, the tendon body and its insertion on the tibial tuberosity, with
10 the subject in supine position, with 20° knee flexion, and a pillow under the knee. The
11 presence of degenerative signs compatible with the medical diagnosis of PT (thickness of
12 the tendon, hypoechoic areas, irregularities affecting the cortical bone, calcifications) that
13 could be relevant for the selection of the target area will also be assessed. In addition,
14 CD-US assessment will be carried out to detect the presence of hypervascularization, with
15 the subject in supine position and with the knee relaxed in full extension, in order to obtain
16 further information to specifically define the target area.
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35 Upon completion of the evaluation, a jump test will be carried out, measured with a force
36 platform (FP4060-10-2000, Bertec Corporation). In this evaluation, subjects will warm
37 up during 5 minutes on a treadmill, subsequently, they will perform dynamic stretches for
38 the leg muscles. The Jump test will be explained to participants and they will be asked to
39 demonstrate how they will perform the assessment to ensure that they have understood it
40 before going to the platform. Later, patients will go to the platform forces and will
41 perform each jump 3 times (squat jump, Abalakov jump and countermovement jump test)
42 with 60 seconds between jumps and 2 minutes between different jumps (Table 1)(26-28).
43 The maximum height of the jump will be analyzed via the measurement of the flight time
44 recorded on the force platforms, the eccentric power and the maximum concentric force
45 performed. The Abalakov jump will be performed with the subject standing in an upright
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3 position with a full arm swing. A rapid downward movement will be immediately
4 followed by a rapid upward vertical movement as high as possible, all in one sequence.
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6 The same procedure will be applied for the CMJ jump, however, this test will be
7 performed with the hands on the hips to avoid arm swings. Finally, a Squat Jump will be
8 performed with 90 degrees of flexion of the knee.
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17 **Participant timeline**

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19 The study design will be a double-blind randomized controlled trial. The flow chart of
20 the trial is shown in Figure 1 and the check list SPIRIT schedule is shown in Figure 2.
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26 **'Patient and Public Involvement'**

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28 Patients with PT were not involved in setting the research question or the outcome
29 measures, however the concept of patient involvement translated to the execution phases
30 of the research. Patients and their families were central to the dissemination of the
31 information, which helped to recruit study participants. We intend to disseminate the main
32 results to trial participants and will seek patient and public involvement in the
33 development of an appropriate method of dissemination.
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45 **Sample size**

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47 Regarding the sample size, a calculation of statistical power was made prior to the study.
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49 Accepting an alpha risk of 0.05 and a beta risk in a bilateral contrast, 19 subjects are
50 needed in every treatment group to detect a difference equal or superior to 15 points on
51 the VISA-p scale and assuming a standard deviation of 15 points(29). The estimated rate
52 of loss to follow-up is 20%.
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3 Recruitment of subjects for the trial will take place between October 2018 and March
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5 2020 and will be carried out by means of informative campaigns targeted at different
6
7 Sports Clubs and Federations by means of e-mail and advertisements in the different
8
9 University mass media.

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12 The interested subjects will receive an e-mail explaining the inclusion and exclusion
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14 criteria, as well as the purpose of the study. If they meet the defined criteria, they will be
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16 invited to send us their medical diagnosis.
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21 **Recruitment**

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23 Participants will be recruited from sports clubs by the physiotherapist or the coach.
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25 Contact has been made with various orthopedists who will collaborate with recruitment,
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27 so that when they establish a diagnosis of this pathology in their examination room they
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29 can refer us to the patients for their recruitment to the study.
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35 **Allocation**

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37 Participants will be randomly assigned to either CG or DN-G or PNE-G with a 1:1:1
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39 allocation using an opaque envelope, with a block size of fifteen participants (5 for each
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41 group).
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44 Sealed opaque randomization envelopes with a study-specific participant number will be
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46 supplied by an external statistician. A colleague not involved in the research study will
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48 take the sealed opaque numbered envelopes in order, by number, and deliver the correct
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50 envelope to the treating physical therapist. The envelope will contain a piece of paper,
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52 which will be labelled with the same participant specific number, plus the group
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54 assignment (PNE-G, DN-G or CG).
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3 Participants who fulfill the inclusion criteria will receive the standardized oral and written
4 information, and, once they grant their consent to take part in the trial, they will be
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6 randomized into the three groups.
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10 11 12 **Blinding**

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14 Assessments regarding clinical recovery will be conducted by an assessor blinded to
15 treatment allocation. Due to the nature of the intervention, participants can be blinded to
16 allocation. Patients will be explained that they are going to receive a needling treatment,
17 that it may be slightly painful, and that if at any time they are unable to tolerate the pain
18 they must inform the researcher to stop the intervention. In order to blind patients, all the
19 interventions were made with the ultrasound and the PNE device connected to simulate
20 the same intervention in all groups. In contrast, the physiotherapist performing the
21 intervention cannot be blinded, however he/she will be instructed not to disclose the
22 allocation status of the participant at any time or during the follow up assessments. An
23 employee outside the research team will feed data into the computer in separate datasheets
24 so that the researchers can analyze data without having access to information about the
25 allocation.
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42 With the intention of evaluating patient blinding, an online questionnaire will be sent to
43 participants upon completion of the study, asking them about the treatment they received.
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49 **Data collection methods**

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51 For the data collection, an oral questionnaire will be used containing questions targeted
52 at collecting baseline data and information concerning the pathology.
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3 Different questionnaires and assessment scales (VISA-p, VAS, SF-36) in Spanish will
4
5 be given to each participant in paper when they attend the assessment, and they will be
6
7 granted sufficient time to complete the same.
8
9

12 **Data management and statistical analysis**

14 In this study, all data will be entered electronically in the assessment room.

16 Original scales and questionnaires will be entered and kept on a locked file at the
17
18 participating site.
19

21 Participant files are to be stored in numerical order and stored in a secure and accessible
22
23 place and manner. Participant files will be maintained in storage for a period of 2 years
24
25 after completion of the study.
26

28 The statistical analysis will be carried out by an intention-to-treat analysis. Variables will
29
30 be described in number (percentage) and average (standard deviation) or median
31
32 (interquartile range) attending to their distribution. Quantitative variables will be
33
34 analyzed with the Shapiro Wilk test in order to confirm their distribution and to determine
35
36 correct statistical tests according to these results.
37
38

39 Outcomes will be analyzed using mixed linear and logistic regression models considering
40
41 participants as a random effect and group of treatment as fixed factors. Baseline
42
43 characteristics will be introduced in the model as covariance. Numbers needed to treat
44
45 index will also be calculated. The primary aim of the analysis will be to calculate the
46
47 difference obtained in the VISA-p score after the intervention (final measurement - initial
48
49 measurement). Finally, the magnitude of the effect of the result will be calculated and
50
51 therefore its clinical importance, by means of the following formula:
52
53

$$54 \quad I^* = \sqrt{\frac{F(1,dfR)}{F(1,dfR) + dfR}}$$

56 The significance level set for all the analysis will be $p \leq 0.05$.
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ETHICS AND DISEMINATION

The study design, procedures and informed consent procedure were approved and consequently the study will be carried out in compliance with the Helsinki Declaration of Human Rights. All participants will have to provide written Spanish informed consent.

Appendix 1.

The results for this trial will be published in peer-reviewed international journals or otherwise made publicly available and will be presented at national and international conferences and symposiums irrespective of the outcomes.

Any modifications to the protocol, which may impact the study procedures, potential patient benefits or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendments will be approved by the Ethics Committee prior to implementation and notified to the health authorities in accordance with local regulations.

All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored identified by code number. All local databases will be secured with password-protected access systems.

Availability of data and material: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

DISCUSSION

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3 This study seeks to investigate the effects of physiotherapy needling techniques on pain,
4
5 functionality and quality of life in PT.
6

7
8 PT is a common cause of knee pain in cases of degeneration of the patellar tendon. Among
9
10 the causes of PT, extrinsic factors (e.g., patellar tendon loading with exercise) and
11
12 intrinsic factors (e.g., malalignment, high patella, imbalances) have been proposed(30).
13
14 Traditionally, the focus has been on quadriceps strengthening exercises and many reviews
15
16 have shown that the effect of the treatment could be estimated to give the patients a 50-
17
18 70% change of improvement on pain and functionality(6, 31, 32).
19

20
21 Regarding needling treatment, previous studies have shown a great improvement in PT
22
23 using PNE in combination with EE, with all patients reporting an improvement at least
24
25 one month after treatment(12-14, 18). This is an improvement compared to the minimum
26
27 three months needed to improve symptoms by applying other conventional techniques
28
29 (pharmacological and biological treatments, cold/heat techniques, shock waves, etc.)
30
31 Additionally, in a long-term study conducted in 2013, this technique was shown to
32
33 improve symptoms quickly and steadily for at least 10 years(33). These findings
34
35 demonstrate that this technique ensures that patients remain pain-free for a long period.
36
37 Furthermore, we were only able to find four articles(12-14, 18) addressing the application
38
39 of PNE for the recovery of PT, however, none of the articles studied were RCTs, which
40
41 entail limited evidence of the effectiveness of this technique.
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47 In addition, there are no standardized protocols for the application of PNE, which explains
48
49 the great variability in the number of sessions and application time based on the literature.
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51 Therefore, this study aims to facilitate clinical practice and combine the available
52
53 methodology criteria in the application of this promising technique.
54

55
56 Regarding DN, the literature shows many similarities with PNE, since there is only one
57
58 RCT that compares functionality improvements among patients who have received PRP.
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3 This study reflected that in the short term PRP had better results for pain and functionality,
4
5 however, DN was more effective than PRP after six months(34).
6

7
8 For the application of both needling techniques, US-guidance is normally used to be able
9
10 to observe firstly the presentation of the tendon, and later to observe the needle and enable
11
12 a much more specific treatment approach. However, US has disadvantages including its
13
14 operator dependence and the limited ability to rule out intra-articular disease. The
15
16 sensitivity and specificity of ultrasonography for patellar tendinopathy is between 58%
17
18 and 94%, respectively(35).
19
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22 Moreover, functionality of the tendon is usually measured with the VISA-p(36,37),
23
24 whereas jump tests (representing a similar action to that performed in subject's daily
25
26 sports) are only evaluated in a few papers(27,38). Countermovement jumps and squat
27
28 jumps are the most reliable and valid field tests for the estimation of the explosive power
29
30 of the lower limbs in physically active men(39). Thus, we will combine both, in order to
31
32 be more accurate in the assessment of the tendon's functionality, and be able to assess
33
34 changes that may affect their sport performance.
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38 This study has several strengths. First, we will evaluate two techniques that currently lack
39
40 strong evidence. However, in doing so, we are contributing to new knowledge in the field
41
42 of the recovery of musculoskeletal injuries. Second, the role of invasive techniques will
43
44 be determined by comparing the effects between these techniques and a control group.
45
46 The reliability of data is ensured, as both patients and the assessor will be blinded. Third,
47
48 a sub-analysis with US will be performed to investigate changes in the presence of
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50 calcifications, cortical irregularities, neovascularization, thickness, eco-intensity, eco-
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52 variation and eco-texture of the patellar tendon.
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3 However, there are some limitations to this study. Blinding of the physiotherapist
4 performing the intervention is not possible. Furthermore, follow-up is limited to 22 weeks
5 after baseline.
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10 The findings obtained may help advance the treatment of this injury by identifying the
11 most effective treatment protocol and to avoid the associated consequences, such as the
12 prevention of relapses and reducing the potential impact on the musculoskeletal system.
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10 **AUTHOR'S CONTRIBUTIONS**

11 MPL, EMG and PH conceived of the idea, and developed the intervention. MPL and PH
12 wrote the article. MPL, MO, RMG, AVB, ZA, YH and PH developed the design of the
13 trial. MO were involved in development of the statistical analysis of the trial and
14 contributed to the content of the article. AVB contributed to the design and writing of the
15 jump test protocol. All authors have read and approved the final manuscript.
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28 **FUNDING STATEMENT**

29 This research received no specific grant from any funding agency in the public,
30 commercial or not-for-profit sectors.
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36 **COMPETING INTEREST STATEMENT**

37 The authors declare that they have no competing interests.
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40 Competing interest: None declared.
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TABLES

Table 1. Jump test's protocol.

JUMP TEST PROTOCOL	
5-minute warm-up consisting of steady jogging on a treadmill	
Dynamic Stretches lasting 5 minutes, as instructed by the physical therapist	Psoas Quadriceps Gluteus maximus Gastrocnemius Hamstring muscles
Three jump tests are performed - 3 jumps off the ground for 3 times for the patient to become familiar with the tests - The subject is placed on the platform and asked to perform each test 3 times, with 60 seconds rest between the different tests	Abalakov test Countermovement jump test Squat jump
The highest jump is selected for the study	

FIGURES

Figure 1. Flow diagram. Randomized controlled trial design.

G-PNE: Percutaneous Needle Electrolysis Group. G-DN: Dry Needle Group.

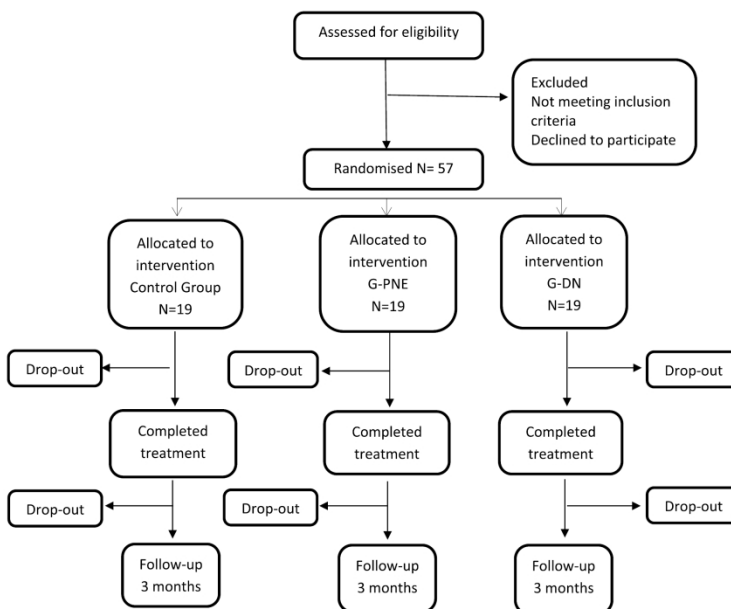
Figure 2. Schedule for the enrolment and intervention.

Schedule for enrolment and intervention per cluster. -t1: baseline; t1-t2: intervention period; t2: 8 weeks after baseline; t3: 10 weeks after baseline; t4: 3 months after baseline. G-PNE: Percutaneous Needle Electrolysis Group; G-DN: Dry Needle Group; US: ultrasound.

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For peer review only

Figure 1. Flow diagram. Randomized controlled trial design.



210x297mm (300 x 300 DPI)

Figure 2. Schedule for enrolment and intervention.

	Enrolment	Allocation	Close-out			
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	t_4
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
<i>Control group</i>			↔			
<i>G-PNE</i>			↔			
<i>G-DN</i>			↔			
ASSESSMENTS:						
<i>Baseline demographic information</i>	X					
<i>VISA-P</i>	X		X		X	X
<i>VAS</i>			X		X	X
<i>SF-36</i>			X		X	X
<i>Tendon structure US</i>			X		X	X
<i>Jump test</i>			X		X	X

215x279mm (300 x 300 DPI)

DOCUMENTO DE INFORMACIÓN AL PACIENTE

Fecha:

Título del proyecto: “ESTUDIO COMPARATIVO ENTRE TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Investigador principal:

Doña: M^a Pilar López Royo

Este estudio se basa en el estudio comparativo de tratamientos que utilizan distintas técnicas de fisioterapia invasiva junto con un programa de ejercicio excéntrico para el tratamiento de la tendinopatía rotuliana. Por medio del tratamiento se produce una disminución del dolor asociado a esta patología y un aumento de la fuerza de la pierna, lo que a su vez hace que mejore la funcionalidad en las actividades de la vida diaria y mejore la calidad de vida.

PROCESO DE SELECCIÓN DE PACIENTES

Criterios de inclusión:

- Edad comprendida entre 18 y 40 años.
- Practicar cualquier deporte de forma habitual.
- Pacientes con diagnóstico médico de tendinopatía rotuliana crónica con un mínimo de 3 meses de evolución y con sintomatología.
- Dolor a la palpación del tendón en el polo inferior de la rótula y durante el entrenamiento o competición.
- Puntuación del cuestionario VISA-P menor de 80 (el resultado obtenido de rellenar el cuestionario tiene que ser menor de 80 puntos de los 100 posibles para poder participar en el estudio).

Criterios de exclusión:

- Paciente operado de la rodilla afectada en los últimos 6 meses.
- Infiltraciones en la rodilla afectada en los últimos 3 meses.
- Paciente que ha recibido tratamiento farmacológico o fisioterápico en las últimas 48 horas o durante el estudio.
- Patología con menos de 3 meses de evolución.
- Presentar tendinopatía rotuliana bilateral.
- Puntuación del cuestionario VISA-p mayor o igual de 80 (el resultado obtenido de rellenar el cuestionario no puede ser igual o superar los 80 puntos de los 100 posibles, sino no podrá participar en el estudio).
- Imposibilidad para aplicar alguna de las técnicas de tratamiento o valoración por

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2 contraindicación absoluta o relativa.
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7 **PROCEDIMIENTO**

8 El tratamiento consiste en realizar un protocolo de ejercicios excéntricos de cuádriceps que
9 realizará en casa de forma diaria, y que serán revisados con el fisioterapeuta para valorar su
10 correcta realización. Se complementará el tratamiento con la aplicación de una técnica de punción
11 según el protocolo de tratamiento propuesto de forma totalmente **aleatorizada** y según los
12 criterios diagnósticos específicos de la misma, siguiendo las indicaciones, criterios de aplicación y
13 criterios diagnósticos.
14

15 Son técnicas de punción cuyo objetivo es producir una respuesta inflamatoria aguda que active los
16 mecanismos fisiológicos de regeneración del tejido y mejorar el dolor y la funcionalidad en la
17 articulación de la rodilla, se realiza con agujas de punción seca, similares a las agujas de
18 acupuntura y sin infiltrar ningún tipo de sustancia dentro del organismo.
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25 Los registros serán realizados en el Espacio de Valoración Funcional de la Universidad San Jorge,
26 en la Facultad de Ciencias de la Salud, Edificio III. Se pondrá a su disposición la posibilidad de
27 utilizar el autobús que utiliza el personal y alumnado de la universidad (en el horario que éste esté
28 disponible). Las fechas y horarios serán convenidas con cada participante en función de su
29 disponibilidad y la de los investigadores, buscando la conformidad de todos. La duración
30 aproximada del estudio para cada paciente será de 30 minutos, aunque este horario podrá variar
31 en función de los acontecimientos.
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38 Será recibido por los miembros del equipo de investigación y una vez allí, se le realizará un primer
39 análisis fisioterápico, rellenará una encuesta, una escala analógica visual (EVA) del dolor y el
40 cuestionario Visa-p en el que se valorará la funcionalidad de la rodilla.
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43 Tras éste primer registro se le colocará un marcador pasivo en el pantalón. Se le pedirá que
44 realice el siguiente protocolo:
45

- 46 - Calentamiento de 5 minutos en cinta a ritmo constante.
- 47 - Estiramientos dinámicos de psoas, cuádriceps, glúteo, gastrocnemios, isquiotibiales durante 5
- 48 minutos instruidos por el fisioterapeuta.
- 49 - Realización de los 3 saltos fuera de la plataforma durante 3 veces para que se familiarice con los
- 50 tests.
- 51 - En la plataforma de fuerzas realizará 3 test de salto: el test de Abalakov (ABK), el test de salto
- 52 con contramovimiento (CMJ) y el squatjump (SJ).
- 53
- 54 Se colocará en la plataforma y realizará 3 saltos de cada uno de los test con una separación entre
- 55 ellos de 60 segundos.
- 56
- 57 Se valora el tendón por ecografía, y se recogen datos por medio de personal adiestrado y se envía
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1 a personal especialista en radiodiagnóstico.

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3 Tras los registros de los saltos se dará por finalizada la valoración.

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6 Tras la 1ª valoración, se realizará una división en tres grupos de los pacientes de forma
7 aleatorizada.

8
9 Se le realizará el protocolo de tratamiento de fisioterapia invasiva que le haya correspondido.
10 Realizará una sesión del tratamiento cada 14 días, y se realizará la 2ª valoración 1 semana más
11 tarde de la 4ª sesión de punción para valorar los cambios que se hayan producido tras el
12 tratamiento, repitiéndose de nuevo el proceso de recogida de datos realizado al inicio del estudio.
13 Se realizará un seguimiento a los tres meses de la valoración post-tratamiento para valorar la
14 eficacia de la técnica a largo plazo del tratamiento.

15
16 El procedimiento se realizará guiado ecográficamente para asegurar la especificidad de aplicación
17 sobre la zona relevante de tratamiento y garantizar la seguridad de la técnica. Se hace posterior a
18 esta intervención una serie de ejercicios excéntricos de cuádriceps. El tratamiento se realizará
19 durante 4 sesiones (a razón de una sesión cada 14 días).

26 **RIESGOS**

27 La aplicación de las técnicas de punción utilizadas no han demostrado tener ningún efecto
28 secundario hasta la fecha, aunque el paciente puede experimentar dolor durante y tras la punción,
29 generalmente de uno o dos días de duración.

34 **RESPONSABILIDADES DEL PARTICIPANTE**

35 La información que usted posea sobre su estado de salud o sobre sensaciones previas
36 anormales al realizarle una punción, puede afectar la seguridad o el valor de estas pruebas. La
37 rápida comunicación por su parte de las sensaciones que experimenta al realizar esta prueba es
38 también de gran importancia. Usted es responsable de revelar esa información al personal de la
39 prueba cuando se le pregunte.

45 **PREGUNTAS**

46 Le animamos a que haga cualquier pregunta sobre los procedimientos seguidos o sus resultados
47 en la prueba. Si tiene alguna preocupación o pregunta, por favor pídasenos más información, para
48 ello le dejamos un correo electrónico mapilr86@hotmail.com y un número de teléfono móvil:
49 616102365.

54 **LIBERTAD PARA DAR EL CONSENTIMIENTO**

55 Usted participa en el estudio de manera voluntaria, pudiendo abandonarlo en el momento
56 que considere oportuno, sin que esto conlleve ninguna repercusión negativa para usted.

57 Los datos obtenidos en el estudio serán confidenciales y únicamente se hará uso de ellos

1
2 para el cumplimiento de los objetivos planteados en la investigación. No se cederán estos datos a
3
4 terceros sin el consentimiento expreso de los sujetos participantes a quienes pertenezcan los
5
6 datos.

7 En esta investigación se garantizará el anonimato de los sujetos que aportan los datos,
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9 estableciendo un código disociado para identificarlos que sólo será conocido por los responsables
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11 de la realización del trabajo de campo.
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17 Fdo: M^a Pilar López Royo
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MODELO DE CONSENTIMIENTO INFORMADO

Título del PROYECTO: “ESTUDIO COMPARATIVO ENTRE TÉCNICAS DE PUNCIÓN PARA EL TRATAMIENTO DE LA TENDINOPATÍA CRÓNICA DEL TENDÓN ROTULIANO”

Doña: M^a Pilar López Royo (mapilr86@hotmail.com)
Departamento de Fisiatría y Enfermería
UNIVERSIDAD DE ZARAGOZA

Yo, (nombre y apellidos del participante)

He recibido suficiente información en relación con el proyecto, he leído la hoja de información que se me ha entregado y he podido hacer preguntas sobre el proyecto, recibiendo respuestas satisfactorias.

Entiendo que la participación es voluntaria y que puedo abandonar el proyecto:

- . Cuando lo desee
- . Sin tener que dar explicaciones
- . Sin que esto repercuta en mis cuidados médicos

He sido claramente informado de forma clara y precisa del tratado que recibirán mis datos personales que se contienen en este proyecto, sabiendo que los datos serán tratados y custodiados bajo mi intimidad y a la vigente normativa de la protección de datos, y que sobre estos datos me asisten los derechos de rectificación, acceso y oposición comunicándolo al investigador principal que figura en este consentimiento.

Declaro que presto libremente mi conformidad para participar en el estudio.

Deseo ser informado sobre los resultados del estudio: sí no (marque lo que proceda)

Así pues, acepto que las muestras derivadas de este proyecto puedan ser utilizadas en futuras investigaciones siempre y cuando están relacionadas con ésta.

Por lo tanto, doy mi conformidad para que mis datos clínicos sean revisados por personal ajeno al centro, para los fines del estudio, y soy consciente de que este consentimiento es

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revocable.

Firma del participante: _____

Fecha: _____

He explicado la naturaleza y el propósito del proyecto al paciente mencionado

Firma del Investigador: _____

Fecha: _____

Consentimiento informado estudio _____

Versión _____, fecha _____

Appendix 2. Checklist SPIRIT



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1-3
	2b	All items from the World Health Organization Trial Registration Data Set	2-3
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	22
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-5
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5-6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11-12
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	12
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13

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4	Implemen	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	13
5	tation			
6	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	13
7	(masking)			
8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
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13	Methods: Data collection, management, and analysis			
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15	Data	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-14
16	collection			
17	methods			
18		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
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22	Data	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
23	management			
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30	Statistical	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
31	methods			
32		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
33				
34		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
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39	Methods: Monitoring			
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42	Data	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	-
43	monitoring			
44		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	-
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51	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	-
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55	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
56				
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58	Ethics and dissemination			
59				
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Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	15
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	15
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	15
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	15
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	-
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	-
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

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