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Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

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3 1 **1. Title:** Cost-Utility of Rotator Cuff Repair Surgery by Open and
4
5 2 Arthroscopic Techniques: Study Protocol for a Randomized Clinical
6
7 3 Trial
8
9

10 4 **1a.Short title:** Cost-utility of open and arthroscopic rotator cuff
11
12 5 repair
13
14

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17 29 **2. Abstract**

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19
20 30 Introduction: Rotator cuff injuries account for up to 70% of
21
22 31 pain in the shoulder girdle. However, there is still no consensus
23
24 32 on the best surgical treatment of patients with rotator cuff
25
26 33 injuries, regarding the cost-effectiveness and cost-utility
27
28 34 analysis between the open and arthroscopic methods of rotator cuff
29
30 35 repair. The objective of this trial is to compare the efficacy,
31
32 36 cost-effectiveness and cost-utility of open and arthroscopic
33
34 37 procedure for rotator cuff repair.

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36
37 38 Methods and Analysis: The trial is a two-group, parallel
38
39 39 design, randomized controlled trial. A total of 100 patients with
40
41 40 symptomatic rotator cuff lesion will be allocated in either open
42
43 41 or arthroscopic technique in a 1:1 ratio, considering smoking (yes
44
45 42 or no), lesion size (less than 3 cm or more than 3 cm) and diabetes
46
47 43 (present or absent) as stratification factors. All patients will
48
49 44 be included in the same rehabilitation program after the
50
51 45 intervention. The primary outcome measure will be the Constant-

1
2
3 46 Murley score at 48 weeks post-surgery. Secondary outcomes include
4
5 47 cost-effectiveness, cost-utility, pain, complications and clinical
6
7 48 analysis, using the EuroQol 5-D3L, the simple shoulder test (SST),
8
9 49 Visual Analogue Pain Scale (VAS), integrity of the repair evaluated
10
11 50 through magnetic resonance imaging, complications and failures of
12
13 51 the proposed methods. For the cost-effectiveness analyses, we will
14
15 52 use the VAS and the Constant-Murley Score as measures of
16
17 53 effectiveness; for the cost-utility analyses, we will use the
18
19 54 EuroQol- 5D-3L as a measure of utility in terms of incremental
20
21 55 cost per quality-adjusted life-years (QALY).
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26 56 Ethics and Dissemination: the study is approved by Research
27
28 57 Ethics Committee. The results will be published in a peer-reviewed
29
30 58 journal.
31
32

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34 59 Trial Registration Number: NCT04146987
35
36

37 60 Keywords: rotator cuff; surgery; arthroscopy; open repair; cost-
38
39 61 effectiveness; QALY
40
41

42 **Article Summary**

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- 45 63 • Few studies evaluate the cost-utility of rotator cuff repair
46
47 64 surgery techniques
 - 48
49 65 • This article will detail the protocol for a randomized
50
51 66 controlled trial comparing the two techniques of rotator cuff
52
53 67 repair.
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68 **Strenghts and limitations of this study**

- 69 • This study is a prospective, randomized trial, that is the
70 best design to address the study question.
- 71 • It will provide surgeons and healthcare providers with
72 important information about the surgical technique and the
73 cost-effectiveness and cost-utility of these techniques
- 74 • The lack of blinding of the patient and surgeons is a
75 limitation to the study design

76 **4. Introduction**

77 **4a. Background and Rationale**

78 Musculoskeletal injuries are a major cost to the healthcare
79 system. In 2004, 30% of the North American population had some
80 kind of musculoskeletal disorder that required medical treatment;
81 between 2002 and 2004, the estimated cost of treating these changes
82 was \$510 billion. Shoulder diseases represent the third most common
83 cause of these changes, behind only spinal and knee disorders [1],
84 [2].

85 An evaluation of the primary health care system in Cambridge,
86 United Kingdom, showed that the average frequency of shoulder pain
87 was 9.5 per 1,000 individuals [3]. Of these, 86% had rotator cuff
88 tendinopathy. North American data estimate that approximately 4.5

1
2
3 89 million patients annually seek medical attention due to shoulder
4
5 90 pain; of these, two million have some symptoms related to the
6
7 91 rotator cuff. About 250,000 rotator cuff repair surgeries are
8
9 92 performed annually in the United States of America (US), and with
10
11 93 the continued increase in life expectancy and aging, there is a
12
13 94 tendency to increase this number [1], [2].
14
15
16

17 95 The rotator cuff is a group of four muscles and their tendons
18
19 96 that act to stabilize the shoulder and allow for its extensive
20
21 97 range of motion. Four muscles and their attached tendons make up
22
23 98 the rotator cuff: the subscapularis, supraspinatus, infraspinatus,
24
25 99 and teres minor. The long portion of the biceps tendon also
26
27 100 contributes to cuff function, which is to stabilize the humeral
28
29 101 head in the glenoid cavity, preventing superior migration of the
30
31 102 humeral head [4].
32
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35

36 103 The possible injuries range from tendon degeneration
37
38 104 (tendinosis/tendinopathy), through partial tear (articular,
39
40 105 interstitial or bursal), to complete tear. Diagnosis is made by
41
42 106 associating history and physical examination along with imaging
43
44 107 methods, and magnetic resonance imaging (MRI) is considered the
45
46 108 method of choice [5]-[13].
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49

50 109 Currently, the indication for surgical treatment is based on
51
52 110 the persistence of symptoms and/or the degree of muscle weakness
53
54 111 and/or size of the tear, after a time of conservative treatment.
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1
2
3 112 In general, when opting for surgery, imaging can assist in the
4
5 113 planning of surgical treatment, since it allows measuring the
6
7 114 extent of the tear (partial or total) and discriminating which
8
9 115 tendons are involved (supraspinatus, infraspinatus, etc.).
10
11
12

13 116 Treatment of rotator cuff tear depends on the type of injury,
14
15 117 the patient's functional capacity, age, and the presence of
16
17 118 symptoms. In general, tendon degeneration and partial tears are
18
19 119 treated non-surgically, with physiotherapy, injections and
20
21 120 analgesic medications. Complete and incomplete tears that did not
22
23 121 respond well to conservative treatment, however, should be treated
24
25 122 surgically [8], [14]-[16].
26
27
28

29 123 Among the surgical options, the open method is still
30
31 124 considered the gold standard, with good or excellent results in
32
33 125 over 90% of cases [17]-[19]. Due to arthroscopy and the evolution
34
35 126 of arthroscopic instruments and implants in the last two decades,
36
37 127 the arthroscopic repair technique has gained space and is widely
38
39 128 used in our country. Some studies [17]-[20] did not show
40
41 129 superiority of one technique over another in terms of clinical
42
43 130 outcomes. On the other hand, since the cost of arthroscopic surgery
44
45 131 is supposedly higher, due to the required equipment, it is
46
47 132 important to establish which option has the best cost-utility
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49 133 ratio. Other published studies suggested that the open method is
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3 134 superior than the arthroscopic method in relation to cost-utility
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5 135 [21]-[23].
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8 136 **4b.Objectives** 9

10
11 137 Despite the high incidence of rotator cuff injury, there is
12
13 138 no consensus about the best method of repair, neither which method
14
15 139 has the cost-effectiveness and cost-utility ratio. Therefore, the
16
17 140 present study aims to compare the open and arthroscopic methods
18
19 141 for rotator cuff repair and determine which presents the best cost-
20
21 142 effectiveness ratio.
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24

25 143 **5.Trial Design** 26

27
28 144 The trial will be a prospective randomized controlled
29
30 145 clinical trial.
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33 146 **6.Methods** 34

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36 147 This randomized controlled trial will follow the Consolidated
37
38 148 Standards of Reporting Trials (CONSORT) Statement [24]; also the
39
40 149 protocol was developed following the SPIRIT guidelines[25]. It
41
42 150 will be performed at Hospital Alvorada Moema (Shoulder and Elbow
43
44 151 Surgery Center of Excellence), São Paulo, Brazil. The cost analysis
45
46 152 will be performed by Hospital Israelita Albert Einstein team, São
47
48 153 Paulo, Brazil.
49
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51

52
53 154 The study has been approved by the local Research Ethics
54
55 155 Committee from both institutions: Hospital Israelita Albert
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1
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3 156 Einstein (CAAE 19182619.3.1001.0071) and Hospital Alvorada Moema
4
5 157 (CAAE 19182619.3.2002.5533).
6
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8 158 All and any modifications in this study will be promptly
9
10 159 reported to all Research Ethics Committee, all institutions, all
11
12
13 160 investigators and all participants.
14
15

16 161 The project is registered in the ClinicalTrials.gov database
17
18 162 (NCT04146987
19
20 163 [https://clinicaltrials.gov/ct2/show/NCT04146987?term=NCT04146987](https://clinicaltrials.gov/ct2/show/NCT04146987?term=NCT04146987&draw=2&rank=1)
21
22 164 &draw=2&rank=1).
23
24
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26 165 The study is sponsored by Fundação de Amparo à Pesquisa do
27
28 166 Estado de São Paulo (FAPESP 2019/02159-3) R. Pio XI, 1500 - Alto
29
30 167 da Lapa - CEP 05468-901 São Paulo/SP - Brasil
31
32 168 Tel: (+55) 11 3838-4000. This institution and the patients enrolled
33
34
35 169 had and will have no role on study design, collection, management,
36
37 170 analysis and data interpretation, writing the report and decision
38
39 171 to submit the report for publication.
40
41
42

43 172 **6a. Sample size**

44
45

46 173 The sample size estimate was obtained to detect differences
47
48 174 between the open and arthroscopic repair groups in relation to the
49
50 175 primary outcome of the study, Constant-Murley Score (CM)
51
52 176 instrument after the intervention. Kukkone's et al. 2013 study
53
54
55 177 [26] estimated the clinically important minimal difference in CM
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3 178 score in 10.4 points in patients with rotator cuff rupture after
4
5 179 3 months of surgical treatment by the arthroscopic method. The
6
7 180 estimated sample size of 45 patients per group, total of 90
8
9 181 patients, would reach 90% power to detect a 10.4 difference between
10
11 182 the groups in the CM instrument post-operative score with a
12
13 183 standard deviation of up to 15 points with a significance level of
14
15 184 5% using a t-Student test. Predicting a loss of around 10% at 12
16
17 185 months of follow-up we aim to recruit 50 patients per group (PASS
18
19 186 software [27]).
20
21
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25 187 **6b. Inclusion criteria**

26
27
28 188 All patients eighteen years of age or older, presenting with
29
30 189 complete rotator cuff injury or a high-grade partial rotator cuff
31
32 190 injury, symptomatic, where conservative therapy failed
33
34 191 (maintenance of pain and disability after conservative treatment),
35
36 192 or the patient could not support the non-surgical treatment. All
37
38 193 patients ought not to have any medical contraindications for
39
40 194 surgery, have a good understanding of the Portuguese language,
41
42 195 agree to participate in the study and sign the Informed Consent
43
44 196 Form.
45
46
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50 197 **6c. Exclusion criteria**

51
52 198 Patients with previous shoulder surgery, previous fractures
53
54 199 in the affected shoulder, those with passive range of motion
55
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1
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3 200 limitation (joint stiffness with an elevation of 90 degrees or
4
5 201 less), radiographic signs of glenohumeral osteoarthritis or
6
7 202 neurologic injury will be excluded. Patients will also be excluded
8
9
10 203 if they do not wish to participate or are unable to understand or
11
12 204 sign the informed consent form (due to conditions such as cognitive
13
14 205 impairment, or mental illness) or if there are any conditions that
15
16 206 contraindicate any of the surgical methods.

20 207 **6d. Randomization and allocation**

23 208 After eligibility assessment, all patients will be informed
24
25 209 about the nature and purpose of the study and will only be included
26
27 210 after agreeing with the study and signing the informed consent
28
29 211 form, that will be obtained by the surgeon that evaluated the
30
31 212 patient and indicated the surgery. Patients will be consecutively
32
33 213 allocated to one of two proposed treatment methods: open rotator
34
35 214 cuff repair or arthroscopic rotator cuff repair (FIGURE 1). The
36
37 215 software R was used to generate a randomization list, considering
38
39 216 100 patients to be included in the study and the same probability
40
41 217 of allocation for both methods of surgery (open and arthroscopic
42
43 218 repair). The variables will be: smoking (yes or no), the size of
44
45 219 the lesion (≤ 3 cm or > 3 cm) and diabetes (present or absent).
46
47 220 Randomization will be performed by the REDCap platform (Research
48
49 221 Electronic Data Capture - Vanderbilt University) [28][29] after the
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51 222 patient is anesthetized and prepared for the surgery. A person not
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3 223 associated with the study will open the software and acquire one
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5 224 of the two techniques possible and tell the surgeon who will
6
7 225 perform the surgery.
8
9

10 226 **6e. Recruitment**

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12
13 227 All patients that are already treated by the shoulder surgeons
14
15 228 at at Hospital Alvorada Moema (Shoulder and Elbow Surgery Center
16
17 229 of Excellence), São Paulo, Brazil, will be enrolled in. this trial.
18
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21 230 **6f. Blinding**

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24 231 Due to the type of interventions, neither participants nor
25
26 232 treatment providers can be blinded to treatment allocation. The
27
28 233 outcome assessment of the primary and secondary outcomes
29
30 234 (Constant-Murley; EuroQol; VAS and SST), patient-reported
31
32 235 outcomes, will not be blind. One of the authors (RP) will assess
33
34 236 all other clinical outcomes. All primary and secondary outcomes
35
36 237 will be assessed at baseline, 6, 24 and 48 weeks, except for the
37
38 238 VAS which will also be assessed at hospital discharge, 1, 2 and 4
39
40 239 weeks. The statisticians conducting the analyses will be blinded
41
42 240 to the treatment status until the analyses are completed.
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48 241 **6g. Patient and Public Involvement**

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51 242 No patient involved
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243 7. Intervention methods

244 Five surgeons with at least four years of surgical technique
245 experience will participate in this study (EFC, MTCA, RP, BAM,
246 VR). Also, the residents of shoulder and elbow surgery, as well as
247 the residents of Orthopedics and Traumatology from Hospital
248 Alvorada Moema and residents in shoulder and elbow surgery at
249 Albert Einstein Hospital may participate in surgeries.

250 Open surgery: patients will be positioned in a beach chair
251 position with the affected limb pending off the table, allowing
252 manipulation and full range of motion range. After asepsis,
253 antiseptis, and placement of sterile surgical fields, an
254 anterolateral incision will be made in the shoulder in question;
255 the deltoid muscle belly will be gently divided along its fibers
256 until exposure of the subdeltoid / subacromial bursa, which will
257 be partially excised for exposure of the subacromial space and
258 rotator cuff tendons. After mobilization and release of the
259 ruptured tendons and debridement of the rotator cuff footprint,
260 the tendon repair to the bone will be performed using 5.5mm metal
261 anchors, according to the preference and technique chosen by the
262 surgeon. In all cases, the release of the coracoacromial ligament
263 and acromioplasty will be performed.

264 Arthroscopic Technique: the patients will be positioned in
265 lateral decubitus position, with the limb to be operated attached

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3 266 to a skin traction device, which through a traction post and 7
4
5 267 kilograms (kg), will maintain the shoulder in the following
6
7 268 position: abduction of 30 to 60 degrees and flexion of 20 to 30
8
9 269 degrees. After asepsis, antisepsis, and placement of impermeable
10
11 270 sterile surgical fields, a posterolateral incision will be made in
12
13 271 the shoulder for optic introduction, with a 50mmHg pressure pump
14
15 272 and a 0.90 flow, and inspection of the glenohumeral joint. If
16
17 273 necessary, an anterior accessory portal will be performed for intra
18
19 274 articular instrumentation. After joint inspection, the optic will
20
21 275 be introduced into the subacromial space with detachment of the
22
23 276 subacromial and subdeltoid bursa with the trocar. After
24
25 277 visualizing the lesion, an accessory lateral portal will be
26
27 278 performed. With the use of shaver blades, partial bursectomy will
28
29 279 be performed and any adherence to the tendon stumps will be
30
31 280 released, as well as debridement of the rotator cuff footprint.
32
33 281 The tendon will then be reinserted to the bone using metallic 5.5mm
34
35 282 anchors, according to the preference of each surgeon. The technique
36
37 283 used, as well as the suture configuration and type of knot used,
38
39 284 will be defined by the surgeon, according to his preference. After
40
41 285 tendon repair, the coracoacromial ligament will be released, as
42
43 286 well as acromioplasty.
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54 288 **8. Postoperative rehabilitation**

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3 289 All patients will undergo the same postoperative
4
5 290 rehabilitation protocol: use of Velpeau sling for 6 weeks; pendulum
6
7 291 exercises from the second week; active movement and recovery of
8
9 292 the range of motion from the sixth week and strengthening from the
10
11
12 293 twelfth week.
13
14

15 294 The patients will be oriented to perform home exercises and,
16
17 295 as well, to be assisted by a physiotherapist twice a week from the
18
19 296 sixth week of surgery and on. It is expected at the end of treatment
20
21
22 297 the need of about thirty sessions of physical therapy.
23
24

25 298

28 299 **9.Outcomes assessment**

30
31 300 Study data will be collected and managed using REDCap
32
33 301 (Research Electronic Data Capture) hosted at Hospital Israelita
34
35 302 Albert Einstein [28][29]. REDCap is a secure, web-based software
36
37 303 platform designed to support data capture for research studies,
38
39 304 providing: 1) an intuitive interface for validated data capture;
40
41
42 305 2) audit trails for tracking data manipulation and export
43
44 306 procedures; 3) automated export procedures for seamless data
45
46 307 downloads to common statistical packages; and 4) procedures for
47
48 308 data integration and interoperability with external sources.
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52 309 All study participants will be evaluated preoperatively, at
53
54 310 the hospital discharge and 1, 2, 6, 24 and 48 weeks after the
55
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3 311 intervention. The Constant-Murley score, Visual Analogue Scale,
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5 312 EuroQol-5D-3L and the Simple Shoulder Test validated to the
6
7 313 Portuguese language questionnaires will be filled out by the
8
9 314 patient and assessed by evaluators to the assigned intervention.
10
11
12 315

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14
15 316 To prevent loss of follow-up all the patients will be
16
17 317 monitored by REDCap software and alerts will be sent to each
18
19 318 patient near time points defined by the investigators. One week
20
21 319 before every medical consultation and at the twelfth week,
22
23 320 regarding the rehabilitation process. If the patient fails to fill
24
25 321 any questionnaire or does not attend the medical consultations, he
26
27 322 will be contacted by phone and e-mail.
28
29
30

31 323 **10.Primary outcome**

32
33
34 324 The Brazilian Portuguese Version of the Constant-Murley Score
35
36 325 (CM) [30] will be measured preoperatively at 6, 24 and 48 weeks
37
38 326 after the intervention. Research assistants (not blinded to the
39
40 327 study aim) will ask the patients to fill in the validated CM form
41
42 328 for the Portuguese language and measure the range of motion with
43
44 329 a goniometer. The CM scale covers different domains of shoulder
45
46 330 function (pain, activities of daily living, range of motion and
47
48 331 power), punctuating each of them; it ranges from 0 to 100, with
49
50 332 higher scores indicating better function.
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333 **10b. Secondary outcomes**

334 EuroQol-5D-3L (European Quality of Life), a generic score
335 developed to describe health-related quality of life [24] will
336 also be assessed preoperatively, at 6, 24 and 48 weeks
337 postoperatively. This score includes five health domains:
338 mobility, self-care, usual activities, pain/discomfort, and
339 anxiety/depression; each domain has 3 levels: no problem; some
340 problems and extreme problems. In addition, the EuroQol-5D-3L has
341 a visual analog scale where the participant assigns a value between
342 zero and one hundred to his or her own health condition [31]. At
343 the end of its application, EuroQol-5D-3L will provide a unique
344 numerical value that can be used for longitudinal comparison
345 between different time periods.

346 Clinical outcomes will also be assessed by the Simple Shoulder
347 Test (SST), validated for Portuguese [32], preoperatively and at
348 6, 24 and 48 weeks after the procedure. SST is a simple, quick and
349 widely used questionnaire for shoulder function measurement; it
350 consists of 12 dichotomous questions answered by the patient
351 himself. Each positive answer (yes) is given a score; at the end
352 of the questionnaire the percentage of positive answers (score) is
353 made, and the higher the percentage, the better the shoulder
354 function. Other outcomes measured will be VAS (visual analogue
355 pain scale) at hospital discharge, 1, 2, 6, 24 and 48 weeks after

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3 356 the intervention. This scale allows pain intensity to be measured
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5 357 with maximum interobserver reproducibility; it consists of a 10 cm
6
7 358 straight line with the ends determining the limits of pain
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9 359 sensation (no pain; worst pain ever experienced); the distance
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11 360 between zero (no pain) and the patient's demarcation defines the
12
13 361 intensity of pain. Complications and failures of the proposed
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15 362 methods will also be assessed.
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21 363 Failures will be characterized as the need for additional
22
23 364 surgical procedures and/or change of the initially proposed
24
25 365 procedure. Patients who, for any reason, demonstrate treatment
26
27 366 failure or require additional interventions will be followed up
28
29 367 and their results included in the group in which they were
30
31 368 initially randomized, according to the intention to treat
32
33 369 principle.
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39 371 After the 48th week, all patients will be submitted to
40
41 372 Magnetic Resonance Imaging (MRI) of the operated shoulder to
42
43 373 evaluate the integrity and healing of the repair performed.
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49 375 **10c. Cost-effectiveness**

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52 376 Cost-effectiveness and cost-utility analyses will be assessed
53
54 377 by the estimate of direct and indirect costs to the private
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2
3 378 healthcare system at 48 weeks. The perspective adopted in the study
4
5 379 will be the social costs, the direct and indirect medical costs.
6
7
8 380 The set timeframe will be 48 weeks and a discount rate of 5% will
9
10 381 be applied. The costs included in direct medical costs will be:
11
12 382 hospitalization, medical fees, medication; the indirect costs:
13
14 383 costs of absenteeism from work, which will be estimated by the
15
16 384 patient-reported number of days away from work multiplied by the
17
18 385 average wage rate of the current year. The costs will be converted
19
20
21 386 from Brazilian Reais to US dollars and brought to the cost schedule
22
23 387 of the current year, in order to avoid that the effect of inflation
24
25 388 on the medical inputs influences the analysis. For the cost-
26
27 389 effectiveness analyses, the VAS and the CM will be used as measures
28
29 390 of effectiveness. For the cost-utility analyses, the EuroQOL-5D-
30
31 391 3L will be used as a measure of utility. The timetable of outcomes
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33 392 assessment is described on Table 1.
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49 397 **Table 1.** Timetable of assessment

STUDY PERIOD

	Enrolment	Allocation	Post-Allocation					Closure
TIMEPOINT	0	0	Surge ry	1w	2w	6w	24 w	48w
ENROLMENT :								
Eligibility Screen	X							
Informed Consent	X							
CM; EQ-5D, SST; VAS Allocation		X						
INTERVENTIONS								
Open Repair			X					
Arthroscopic Repair			X					
ASSESSMENTS :								
CM; EQ-5D, SST; VAS						X	X	X
MRI	X		X	X	X	X	X	X
Complications			X	X	X	X	X	X
Economics			X	X	X	X	X	X

398

399 11.Data analysis

400 The descriptive analyzes of variables will be based on the
 401 absolute frequencies and percentages for categorical variables and
 402 summary measures as means and standard deviations or medians and
 403 quartiles, as well as minimum and maximum values for numerical

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1
2
3 404 variables [33]. Clinical scores will be represented by individual
4
5 405 profile graphs separately by the surgical technique group.
6
7

8 406 The groups will be compared according to the presence of
9
10 407 categorical clinical outcomes (failures, complications and healing
11
12 408 integrity) by Chi-square or Fisher's exact tests, depending on the
13
14 409 distribution observed after data collection.
15
16

17
18 410 For inferential analysis of numerical clinical outcomes,
19
20 411 mixed models will be used and, if the normal distribution is not
21
22 412 adequate, generalized mixed models will be used [34]. The models
23
24 413 will have time effects (preoperative, 6, 24 and 48 weeks after
25
26 414 intervention), surgical technique group (open repair or
27
28 415 arthroscopic repair) and the interaction effect between time and
29
30 416 group. The size of the lesion (smaller than three cm or larger
31
32 417 than three cm) will also be included in the models as a control
33
34 418 variable, seeking to avoid possible biases.
35
36
37
38

39 419 The analyzes will be performed with the aid of the SPSS
40
41 420 program [35], considering a significance level of 5%.
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45 421

46 47 422 **12. Safety** 48 49

50 423 There will be no benefit to the participant, beyond what is
51
52 424 expected for the correction of the rotator cuff injury, expecting
53
54 425 an improvement of pain and function of the affected shoulder. The
55
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3 426 risks of the present study are those inherent in any surgical
4
5 427 treatment and anesthetic procedure, such as surgical wound
6
7 428 infection, scar formation, pain, shoulder range of motion, rotator
8
9 429 cuff tear, neurovascular injury. If any complications occur, all
10
11 430 patients will be treated by the same surgical team until the
12
13 431 complication is healed.
14
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16
17 432 Both surgical techniques have the same goal, that is, to
18
19 433 repair the ruptured tendon to the bone. The open technique requires
20
21 434 a larger incision, as well as greater surgical dissection and
22
23 435 manipulation of the deltoid muscle, which may cause greater
24
25 436 postoperative pain and weakness of this muscle, in addition to
26
27 437 causing a slightly larger scar. However, it provides great
28
29 438 visualization and manipulation and mobilization capability of the
30
31 439 ruptured tendon, which provides a safer and tension-free repair.
32
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35

36 440 The arthroscopic technique is performed with some point-
37
38 441 shaped cuts in the shoulder, usually three or four; due to smaller
39
40 442 incisions, it requires less muscle manipulation, which
41
42 443 theoretically would cause less postoperative pain and less muscle
43
44 444 weakness of the deltoid muscle, it also has minor scars. However,
45
46 445 this technique requires more surgeon's experience and the
47
48 446 mobilization of the ruptured tendon(s) is limited. Using a large
49
50 447 amount of saline may cause edema in the operated shoulder, which
51
52 448 is usually reversed after the first 12 hours of surgery.
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3 449 Finally, there is a minimal risk of loss of data
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5 450 confidentiality, but the responsible researcher undertakes to do
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7
8 451 everything possible to maintain data confidentiality. One of the
9
10 452 researchers will have access to all data during the entire trial
11
12 453 period. Any adverse event will be reported to the researchers
13
14 454 involved and communicated to the main investigator according to
15
16 455 the Institutional Review Boards description.
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18

19 456 **13.Discussion**

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21
22 457 There is no consensus about the best cost-effectiveness of
23
24 458 surgical treatment of patients with degenerative rotator cuff
25
26
27 459 injuries. Several studies [21], [22], [36], [37] suggest that the
28
29 460 open repair method is more cost-effective than the arthroscopic
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31 461 method, resulting in the same clinical outcome with lower cost.
32
33
34 462 Adla, Deepthi N. et. al [21] in a prospective nonrandomized study,
35
36 463 showed that both techniques lead to the same clinical outcomes.
37
38 464 The costs of arthroscopic surgery were higher than the open
39
40 465 surgery, mainly due to the costs of the suture anchors, which was
41
42
43 466 used only in the arthroscopic group, is important to notice that
44
45 467 in most of the open surgeries, the repair was performed through
46
47 468 transosseous sutures. Köse, Kamil Çağrı et. al [22], in a
48
49 469 retrospective study, also demonstrated similar clinical outcomes,
50
51
52 470 although the costs of arthroscopic procedure being much higher.
53
54 471 Importantly, the open repair technique was performed using
55
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1
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3 472 transosseous sutures and the arthroscopic method using suture
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5 473 anchors and also, the open repair group required longer length
6
7 474 hospital stay. Hui, Yik Jing et. al [36] in a retrospective cohort
8
9 475 study, described a significantly higher cost for the arthroscopic
10
11 476 procedure, compared to the open repair, evaluating only the in-
12
13 477 hospital costs, but with the same clinical outcomes. However, it
14
15 478 is important to emphasize that the open repair was performed using
16
17 479 transosseous sutures, without suture anchors and that the
18
19 480 arthroscopic group needed a longer surgery time. Churchill, R.S.
20
21 481 et. al [37] using the New York Ambulatory Database System, with a
22
23 482 total of 5,224 cuff repair surgeries, of which 1,334 open repair
24
25 483 and 3,890 arthroscopic repair, showed that the mini-open rotator
26
27 484 cuff repair costs significantly less than the arthroscopic repair
28
29 485 and requires significantly less surgical time. However, no
30
31 486 clinical outcomes have been analyzed in this study, making it
32
33 487 impossible to determine the cost-effectiveness ratio. An elegant
34
35 488 study Carr, A.J. et. al [38] carried out as a prospective
36
37 489 multicenter randomized clinical trial, concluded that there is no
38
39 490 difference in the effectiveness and cost-effectiveness between the
40
41 491 open repair surgery and arthroscopic surgery after 24 months of
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43 492 follow-up, even with the higher initial costs in the arthroscopy
44
45 493 surgery. An economic evaluation of the data from this study was
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47 494 carried out, showing that the Incremental Cost Effectiveness
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3 495 (ICER) was uncertain and the arthroscopic repair surgery was
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5 496 slightly more costly and less effective than open repair surgery.
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7

8 497 Thus, despite the high incidence of rotator cuff injury, there
9
10 498 is insufficient evidence to determine the best method for treating
11
12 499 these injuries. So, the present study proposes to answer the
13
14 500 clinical question of which method, open or arthroscopic, presents
15
16 501 the best cost-effectiveness in the surgical treatment of rotator
17
18 502 cuff injury. Providing conclusive, good quality evidence for and
19
20 503 contributing to the evidence base of methods used to treat rotator
21
22 504 cuff injuries.
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27 505 **14.Trial status**

28
29
30 506 Protocol Trial version: 3 Date: 07/24/2020
31
32

33 507 Recruitment Estimated Start Date: August/2020
34
35

36 508 Recruitment Estimated End Date: December/2021
37
38

39 509 Not yet recruiting.
40
41

42 510 **15.Additional files**

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44
45 511 **Table 1.** Timetable of assessment
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47 512 **Figure 1.** Flowchart of participants
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49

50 513 Informed Consent
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3 514 **16. Abbreviations**
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6 515 CONSORT: Consolidated standards of reporting trials; VSA: Visual
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8 516 analogue scale; MRI: magnetic resonance imaging; QALY: quality-
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10 517 adjusted life years; CM: Constant-Murley Score; SST: Simple
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12 518 Shoulder Test
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17 519 **17. Declarations**
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19

20 520 **17.1 Ethics Approval and Consent to Participate**
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22

23 521 The study has been approved by the local Research Ethics Committee
24
25 522 (CAAE 19182619.3.1001.0071). Digital, informed consent to
26
27 523 participate will be obtained from all participants through REDCAP.
28
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30

31 524 **17.2 Consent for Publication**
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33

34
35 525 Not Applicable
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38 526 **17.3 Availability of Data and Materials**
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40

41
42 527 The datasets used and/or analysed during the current study will be
43
44 528 available from the corresponding author upon request.
45
46

47 529 **17.4 Competing interests**
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49

50
51 530 The authors declare that they have no competing interests.
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2
3 531 17.5 **Fundings**
4
5

6 532 This study is supported by Fundação de Amparo à Pesquisa do Estado
7
8 533 de São Paulo (FAPESP 2019/02159-3).
9

10
11
12 534 **17.6 Author contributions**
13

14 535 ML is the Chief Investigator; he conceived the study, led the
15
16 536 proposal and protocol
17
18
19 537 development.
20

21
22 538 RP is the lead trial methodologist and helped in the study
23
24 539 conceiving and development
25

26
27
28 540 EA contributed to study design and to development of the proposal.
29

30
31 541 IO contributes to study design related to QALY
32

33
34 542 IQC is responsible for cost-analysis
35

36
37 543 FM helped in the English translation and registration/publication
38
39 544 of the trial
40

41
42 545 PF helped in the English translation and registration/publication
43
44 546 of the trial
45

46
47 547 EFC helped in the study conceiving and development
48

49
50 548 BAM helped in the study conceiving and development
51

52
53 549 All authors read and approved the final manuscript.
54
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2
3 550 **17.7 Acknowledgements**
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5

6 551 Not applicable
7
8

9 552 **18. Dissemination policy**
10
11

12 553 All the authors are committed and agree to publish the full results
13
14 554 of the research, despite the final results.
15
16

17 555 **19. Data Monitoring Committee (DMC)**
18
19

20 556 Since this trial have a short durations and both surgical
21
22 557 techniques have known minimal risks, there is no need for such
23
24 558 committee.
25
26
27

28 559 **19. References**
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21 22 23 700 **TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO**

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28
29 702 ***Título do projeto:*** *Custo-Efetividade da Cirurgia de Reparo do Manguito Rotador Pelas Técnicas*
30
31 703 *Aberta e Artroscópica. Ensaio Clínico Randomizado.*

32
33
34 704 ***Pesquisadores responsáveis:*** *Mario Lenza e Rafael Pierami*

35
36 705

37 706 O(a) Sr(a) está sendo convidado para participar, como voluntário, de uma pesquisa científica. O Termo de
38 707 Consentimento Livre e Esclarecido tem por meta esclarecer esta pesquisa, explicando resumidamente seus
39 708 objetivos, procedimentos, riscos e benefícios. Após ser esclarecido sobre as informações a seguir, e aceitar fazer
40 709 parte do estudo, rubrique todas as páginas e assine ao final deste documento. Uma via será enviada para o(a) Sr(a)
41 710 por e-mail.

42
43 711

44
45 712 ***Objetivo do estudo:***

46 713 O objetivo deste estudo é avaliar o custo-efetividade (relação da melhora clínica com os custos dos
47 714 procedimentos) de dois tipos de cirurgias para o reparo do manguito rotador: cirurgia aberta e cirurgia artroscópica.

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51 716 ***Descrição do estudo:***

52 717 A ruptura do manguito rotador, ou seja, o rompimento dos tendões do ombro é a principal causa de dor no
53 718 ombro na população adulta, causando, além da dor, diminuição da força no ombro acometido e perda de qualidade
54 719 de vida, devido a dor constante e piora na qualidade do sono causado pela dor. Existem duas técnicas cirúrgicas para

720 correção desta doença: a técnica cirúrgica aberta, realizada por uma incisão (corte) no ombro e visualização direta
721 do tendão rompido; e a técnica cirúrgica artroscópica, realizada através de pequenos cortes no ombro, por onde são
722 introduzidos uma câmara de vídeo, para visualização do tendão rompido e instrumentais para realização da cirurgia.
723 Ainda não há uma definição se há diferença entre os resultados obtidos e as técnicas cirúrgicas utilizadas. O(a) Sr(a)
724 está sendo convidado para participar deste estudo pois há indicação de cirurgia para o reparo do manguito rotador.

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Procedimentos a serem realizados:

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O estudo terá dois grupos de pacientes: grupo que fará a reconstrução do manguito via técnica cirúrgica aberta e o grupo que fará a reconstrução via técnica cirúrgica artroscópica. A seleção dos voluntários será feita de forma randomizada, isto é, não saberemos em que tipo de cirurgia cada indivíduo será incluído. A duração total da pesquisa será de um (01) ano e a participação do Sr(a) será em responder questionários sobre a sua saúde antes da cirurgia, comparecer às consultas médicas, antes da cirurgia e após 6, 24 e 48 semanas da cirurgia e realizar os exames de Ressonância magnética antes da cirurgia e após 48 semanas da cirurgia. Caso o(a) Sr(a) concorde em fazer parte deste estudo, os dados preenchidos e coletados serão utilizados para fins de pesquisa. Importante informar que os pacientes de ambos os tipos de cirurgia receberão os mesmos cuidados e os mesmos seguimentos e que não serão necessários exames de imagem ou laboratoriais adicionais àqueles rotineiramente utilizados para pacientes com lesão do manguito rotador. Como tratamento habitual após a cirurgia de lesão do manguito, o(a) Sr(a) será orientado a realizar um programa de reabilitação que inclui o uso de tipóia do tipo Velpeau por seis (06) semanas e um programa de exercícios pendulares orientados. Após, a tipóia será retirada e o(a) Sr(a) será orientado a realizar exercícios domésticos para ganho de movimento, além de duas sessões semanais de fisioterapia para analgesia e recuperação da amplitude de movimento do ombro. A partir da décima segunda semana (12ª) iniciarão os exercícios de fortalecimento muscular sob orientação de fisioterapeuta. No término do estudo será verificado se houve melhora na função do ombro, na qualidade de vida e na cicatrização do tendão reparado por meio de questionários de simples preenchimento e exame de ressonância magnética.

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Possíveis riscos e desconfortos:

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Os riscos do presente estudo são aqueles inerentes a qualquer tratamento cirúrgico e procedimento anestésico, como infecção da ferida operatória, formação de cicatriz, dor, limitação do arco de movimento do ombro, rerruptura do manguito rotador, lesão neurovascular. A técnica cirúrgica aberta pode provocar maior dor pós-operatória e fraqueza muscular, além de causar uma cicatriz pouco maior. A técnica cirúrgica artroscópica pode causar menos dor pós-operatória e menos fraqueza muscular; além disso, apresenta cicatrizes menores, mas pode causar edema no ombro operado, o que geralmente é revertido após as primeiras 12 horas da cirurgia.

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Benefícios para o participante:

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O(a) Sr(a) não terá benefício além do esperado para a operação de correção da lesão, esperando-se melhora da dor e função do ombro operado, independente do tipo de técnica cirurgia utilizada. A sua participação ajudará a entender qual das técnicas cirúrgicas apresenta o melhor custo-efetividade para o tratamento de lesão do manguito rotador e permitirá apresentar à comunidade médica informações sobre a melhor indicação cirúrgica de tratamento.

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Direitos do participante:

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3 762 Sua participação é voluntária e o(a) Sr(a) pode retirar seu consentimento ou ainda descontinuar sua
4 763 participação em qualquer momento, se o assim o preferir, sem penalização e/ou prejuízo de qualquer natureza. Não
5 764 haverá nenhum custo ao Sr(a) proveniente deste estudo, assim como não haverá qualquer tipo de remuneração
6 765 pela sua participação.

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11 768 Estou ciente que:

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13 769 1. As informações obtidas serão analisadas em conjunto com as de outros voluntários, não sendo divulgada
14 770 a identificação de nenhum participante.

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17 772 2. As informações produzidas neste estudo serão mantidas em lugar seguro, codificadas e a identificação
18 773 só poderá ser realizada pela equipe do projeto.

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22 775 4. Em qualquer etapa do estudo, você terá acesso aos profissionais responsáveis pela pesquisa para
23 776 esclarecimento de eventuais dúvidas. O coordenador do projeto é o Dr. Mário Lenza e o principal responsável pelo
24 777 estudo é o Dr. Rafael Pierami. Os pesquisadores podem ser encontrados nos seguintes endereços: Dr. Mario Lenza
25 778 –Av. Albert Einstein, 627 – bloco A1 – 3º andar – Programa Locomotor, Morumbi, São Paulo – CEP 05652-900: Tel:
26 779 (11) 2151.1444; e-mail: mario.lenza@einstein.br; e Dr. Rafael Pierami –Avenida Ministro Gabriel Rezende de Passos,
27 780 550, 2º andar, Hospital Alvorada Moema – Centro de Excelência em Cirurgia de Ombro e Cotovelo, Moema, São
28 781 Paulo – CEP 04521-022 – Tel: (11) 2186-9810 ou (11) 2186-9809; e-mail: rafael_pierami@hotmail.com.

29
30 782

31 783 Se você tiver qualquer dúvida ética em relação à pesquisa, entre em contato com:

32
33 784 **Comitê de Ética em Pesquisa do Hospital Israelita Albert Einstein** - Av. Albert Einstein 627/701, São
34 785 Paulo/SP, fone 2151-3729, e-mail: cep@einstein.br. Reclamações, elogios e sugestões deverão ser encaminhados
35 786 ao Sistema de Atendimento ao Cliente (SAC) por meio do telefone (11) 2151-0222 ou formulário identificado como
36 787 fale conosco disponível na página da pesquisa clínica ou pessoalmente.

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39 789 **Comitê de Ética em Pesquisa em Seres Humanos do Hospital Pró-Cardíaco (CEP/HPC)** - Tel: (21) 3289-3802
40 790 - Localizado na Rua Voluntários da Pátria, 435/8º andar – Botafogo, Rio de Janeiro/RJ, CEP: 22270-005. Horário de
41 791 atendimento: de segunda à sexta-feira, das 09:00h às 16:00h.

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45 793 Confirmando que li o conteúdo deste Termo de Consentimento Livre e Esclarecido e aceitei participar
46 794 voluntariamente deste estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a
47 795 serem realizados, seus eventuais desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos
48 796 permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia do acesso a
49 797 tratamento hospitalar quando necessário. Concordo voluntariamente em participar deste estudo, sabendo que
50 798 poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou
51 799 prejuízos ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.

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Nome Completo do participante da pesquisa

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Assinatura do participante da pesquisa

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Nome completo e legível do pesquisador responsável

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Assinatura do pesquisador responsável

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Nome completo do representante legal

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Assinatura do representante legal

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For peer review only

HOSPITAL ISRAELITA ALBERT EINSTEIN-SP**UNIFIED REVIEW – ETHICAL AND RESEARCH COMMITTEE****RESEARCH PROJECT DATA**

Project title: Cost-effectiveness of rotator cuff repair surgery by open and arthroscopic techniques: a randomized control trial

Responsible researcher: Mario Lenza

Area:

Version: 2

CAAE: 19182619.3.1001.0071

Proponent institution: SOCIEDADE BENEF ISRAELITABRAS HOSPITAL ALBERT EINSTEIN

Main funding source: SOCIEDADE BENEF ISRAELITABRAS HOSPITAL ALBERT EINSTEIN

TECHNICAL REPORT INFORMATION

REVIEW #: 3.636.334

Project:

This is a randomized clinical trial that will be carried out in two health facilities (Hospital M'Boi Mirim e Hospital Alvorada). The objective is to compare method of repair of the shoulder rotator cuff, open or arthroscopic. The study will be funding by the São Paulo Research Foundation – FAPESP.

Objective of the study:

To compare open or arthroscopic method of repair of the rotator cuff, and determine which method has the best cost effectiveness ratio.

Risks and benefits Assessment:

To respond to the request by the Ethical and Research Committee, in this new version authors describe specific risks for each surgical technique that will be study in the project.

Continuing – report # 3.636.334

Comments and considerations on the study:

Authors have addressed all requested changes. We believe that there is not need to hire a specific insurance, present statement of all participating institutions. Authors will be the solely responsible to treatment of possible adverse events as a result of the study. We also did not included cost of arthroscopy material, once they would exceed the total funding received for this study. For this reason, although the cost of arthroscopy would be included in total of treatment for the responsible institution, there are not real ethical deviation that avoids project execution.

Considerations on mandatory terms and conditions:

Required terms were presented, including the agreeing term of co-participant institution.

The consent form was revised, now its language is clear, and risks for each surgery technique were clarified.

Recommendations:

ERC is responsible to “follow-up the development of projects by providing semester reports to researchers and other monitoring strategies, taking into consideration the risk of the study”. For this reason, the researcher/responsible needs to forward to Einstein’s ERC partial reports every 6 months and a final report of the project, up to 30 days after its conclusion.

Partial report, final report, or study withdrawal or closure:

<https://www.einstein.br/pesquisa/servicos/comite-etica-em-pesquisa/relatorio-pesquisas-aprovadas>

Following the CNS 466/2012 resolution, the responsible researcher must guarantee confidentially and anonymity of procedures, imaging rights, and non-stigmatization of participants of the study, guaranteeing the non-use of information that may harm people and/or communities, including in terms of self-esteem, prestige, and/or finance and economic aspects.

In case of severe adverse events, please consider the guidance in the link:

<http://apps.einstein.br/forms/pesquisa/form-adve.html>

If event related to procedure of the study occurs or medication in use, please, fulfil the Severe Adverse Event from CONEP at

http://conselho.saude.gov.br/web_comissoes/conep/aquivos/FORMULARIO_EAS_CONEP_2011.doc

Conclusion or pending and inadequacy list:

After analysis, the following documents were approved:

1 - Research project – version dated September 27, 2019.

2 - Consent Term – Version 2 dated September 25, 2019.

Continuing – report # 3.636.334

Final considerations and ERC's criteria:

DOCUMENTS APPROVED BY ERC OF THE HOSPITAL ISRAELITA ALBERT EINSTEIN IN A MEETING HELD IN OCTOBER 08, 2019.

This report was elaborated based on the following documents:

Document	File	Upload date	Author	Status
Basic information of the project	PB_INFORMAÇÕES BÁSICAS DO PROJETO_1381072.pdf	27/09/2019 17:47:33		Accepted
Statement of Institution and Infrastructure	Declaracao_de_assistencia_e_responsabilidade_Mboi_Mirim.pdf	27/09/2019 17:45:37	Rafael Pierami	Accepted
Consent form / Absence justification	TCLE.docx	27/09/2019 17:37:41	Rafael Pierami	Accepted
Consent form / Absence of justification	TCLE_sem_demarcacoes.docx	27/09/2019 17:37:23	Rafael Pierami	Accepted
Statement of Institution and Infrastructure	Termo_de_anuencia_Alvorada.pdf	27/09/2019 17:37:03	Rafael Pierami	Accepted
Detailed Project/ Researcher's brochure	Projeto_ECR_Manguito_Aberto_vs_Artroscopico_sem_demarcacoes.docx	27/09/2019 17:35:44	Rafael Pierami	Accepted
Detailed Project/ Researcher's brochure	Projeto_ECR_Manguito_Aberto_vs_Artroscopico_27_09_19.docx	27/09/2019 17:35:30	Rafael Pierami	Accepted
Statement of Researchers	carta_resposta_CEP_HIAE.docx	27/09/2019 17:35:15	Rafael Pierami	Accepted
Statement of Researchers	carta_resposta_CEP_HIAE_assinada.pdf	27/09/2019 17:35:01	Rafael Pierami	Accepted
Statement of institution and infrastructure	declaracao_assistencia_alvorada.pdf	27/09/2019 17:34:39	Rafael Pierami	Accepted
Chronogram	cronograma.xlsx	27/09/2019 17:33:59	Rafael Pierami	Accepted
Statement of Researchers	Declaracao_Resp_Pesq_Mario.pdf	16/08/2019 15:50:58	LETICIA FONSECA DA COSTA	Accepted
Others	AnuenciaGestorAreaMario.pdf	16/08/2019 15:49:39	LETICIA FONSECA DA COSTA	Accepted
Title page	Folha_de_rosto_plataforma_Brasil_ECR_manguito.pdf	12/08/2019 19:08:38	Rafael Pierami	Accepted
Statement of institution and infrastructure	autarquia_mboi_mirim.pdf	12/08/2019 19:07:39	Rafael Pierami	Accepted
Statement of institution and infrastructure	Termo_anuencia_mboi_mirim.pdf	12/08/2019 19:06:09	Rafael Pierami	Accepted

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3 **Status of the report:**
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5 Approved
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7 **Documents requires CONEP evaluation:**
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9 No
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14 October 11, 2019
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18 **Responsible signature:**
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22 **Fabio Pires de Souza Santos (Coordinator)**
23
24

25 _____
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27 **Address:** Av. Albert Einstein 627 - 2ss - Morumbi - SP – Zip Code: 05.652-000
28

29 **Phone:** (11)2151-3729
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31 **Fax:** (11)2151-0273 **E-mail:** cep@einstein.br
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DISPATCH**Grant number** 2019/0259-3**Support type** Regular programs / Research support / Research project / Research project
– Regular – Continuous Flow**Status** Ongoing**Term** June 01, 2019 to May 31, 2021**Grantee** Mário Lenza**Principal investigator** Mário Lenza**DISPATCH PAGE OF THE INITIAL PROPOSAL - REGULAR RESEARCH PROJECT****Result**

Granted

Dispatch date

May 24, 2019

Budgeted amount

Benefits	Requested (R\$)	Dispatched (R\$)
Funds		
Permanent material	0.00	0.00
Costs		
Transportation	0.00	0.00
Daily expenses	0.00	0.00
Consumption material	135,520.00	121,968.00
Third parties	0.00	0.00
Technical reserve for complementary benefits	16,000.00	16,000.00
Technical reserve for Infrastructure	20,328.00	18,295.20
Importing provisioning		
Total	171,848.00	156,263.20

Scholarship quotes

None requested

Project team**Members of the team – requested**

Name	Position	Complementary benefits	Term
Mário Lenza	Principal researcher	Yes	April 1, 2019 – March 31, 2021
Mário Ferreti Filho	Associate researcher	-	April 1, 2019 – March 31, 2021
Isadora Orlando de Oliveira	Technical support	-	April 1, 2019 – March 31, 2021
Rafael Pierami	Technical support	-	April 1, 2019 – March 31, 2021
Ana Claudia Pereira Sanguin	Administrative staff	-	April 1, 2019 – March 31, 2021
Tania Oliveira Lopes	Administrative staff	-	April 1, 2019 – March 31, 2021

Members of the team – dispatched

Name	Position	Complementary benefits	Term
Mário Lenza	Principal researcher	Yes	June 1, 2019 – May 31, 2021
Mário Ferreti Filho	Associate researcher	-	June 1, 2019 – May 31, 2021
Isadora Orlando de Oliveira	Technical support	-	June 1, 2019 – May 31, 2021
Rafael Pierami	Technical support	-	June 1, 2019 – May 31, 2021
Ana Claudia Pereira Sanguin	Administrative staff	-	June 1, 2019 – May 31, 2021
Tania Oliveira Lopes	Administrative staff	-	June 1, 2019 – May 31, 2021

Project planning

Start date: June 1, 2019

Duration: 24 months

End date: May 31, 2021

Field of knowledge: Health

Scientific report (quantity): 2

Scientific report (submission date): May 30, 2020
June 30, 2021

Financial report (quantity): 2

Financial report (submission date): May 30, 2020
June 30, 2021

Category of the research: T/PP [AUTOR, VERIFICAR ACRÔNIMO]

Observations / Transcriptions / Statements

Observations to the responsible

I am pleased to inform that your research grant mentioned above, after careful analysis by the FAPESP committee, has been approved. Please be aware that items in your budget

1
2
3 were revised, and some were not approved, and others were approved but for reduced
4 amount. An e-mail will be sent with instructions for you to confirm the interest in the
5 grant.
6

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8 The use of the grant must follow instructions of the guideline on the use of resources,
9 financial report, and technical reserve.
10

11 Further information about this dispatch is available at “Sistema SAGe -
12 www.fapesp.br/sage .
13

14
15 If you have any questions or need more information about this grant, please use the
16 channel made available for this purpose at "Talk to FAPESP" - www.fapesp.br/converse.
17

18 Sincerely,
19

20 Carlos Henrique de Brito Cruz
21 Scientific director
22

23 **Statements for the responsible**

24
25
26 None
27

28 **Review to the responsible of the proposal**

29 **General analysis of the proposal including 1 – applicant’s academic experience, 2 –** 30 **research project, 3 – budget.**

31
32 This is a good proposal, although the final result of the study is predicted, considering
33 finding of the published in the international literature concerning the costs for each type
34 of surgery. That said, the current proposal can have a positive impact, considering that
35 final result may provide guidance for decision making of future Brazilian surgeries, who
36 may choose the lower cost procedure, however, this is not the only factor to take into
37 account.
38

39
40 The applicant’s academic experience is adequate, especially for his deeply experience
41 with shoulder surgery that can be seen by the studies he published in the area. The project
42 itself is fairly simple but well planned and written, in addition it involves a high number
43 of patients (100 individuals) and surgeons. It is important to note that each surgeon’s
44 preference and bias should be considered, as well as final clinical result. This bias needs
45 to be careful followed-up by the principal researcher in order to prevent high standard
46 deviations.
47
48
49

50 **Please analyze the applicant’s academic experience by considering** 51 **scientific/technological production.**

52
53 As previously mentioned, the applicant’s academic experience is fair. He holds a PhD
54 from UNIFESP for 9 years now, and a post-doctoral degree from university in Australia
55 in 2011. In addition, he is professor at Einstein Medical College for 6 or 7 years. The 10
56 scientific publications listed in his application are all relevant and involved topics of his
57 specialty and correlated areas. The grantee also acts as supervisor in graduate program,
58 including projects with FAPESP funding. His scientific production totalize 57 papers and
59
60

1
2
3 2 book chapters. Currently he supervises two PhD students, and he had completed the
4 supervision of one master-degree student and two PhD student.
5

6
7 **Please specify the applicant's experience with projects related to the area**

8
9 After the analysis of the applicant's CV, I believe his is the leader in his research area at
10 Einstein Medical College. His performance seems adequate, given the graduate
11 supervisions he had completed.
12

13
14 **Please analyze the applicant's ability to educate new researchers**

15
16 As stated above, the applicant performance in this regard is adequate.
17

18
19 **If applicable, please analyze the performance of applicant with previous funding
20 requests submitted to FAPESP**

21
22 Not applicable
23

24
25 **Provide/analyze other relevant issue of the applicant's academic experience**

26
27 None to report
28

29
30 **Applicant's academic experience – Final assessment**

- 31 () Excellent
32 (x) Very good
33 () Good
34 () Fair
35 () Inadequate
36

37
38 **Please analyze research project, considering the following:**

39
40 **Originality and contribution to the research area**

41
42 As stated above, the results of the present study are somewhat predictable, but the topic
43 is relevant, especially for the focus on less costly surgical procedure that is adequate for
44 the reality of our country.
45

46
47 **Theoretical framework and methodology**

48
49 The project is simple, perhaps, this is reason why the results will be efficient. Of note are
50 the bias problem due to the personal preferences of surgeons, and the need to equalize as
51 much as possible these preferences in order to prevent unnecessary deviations in cost of
52 the procedures. Another issue is the type implants to be used. Implants need need to be
53 the same to all patients, whenever possible.
54

55
56 **Funding for technical training**

57
58 None to report
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3 **Total funding requested justifies the scientific and technological relevance of the**
4 **project**

- 5
6
7 (x) Yes
8 () No
9

10
11 **Project term is adequate for the project development**

- 12
13
14 (x) Yes
15 () No
16

17 **Infrastructure of the institution where the study will be conduct adequate**

- 18
19 (x) Yes
20 () No
21

22 **Project will include scientific initiation and graduate students**

- 23
24
25 (x) Yes
26 () No
27

28 **Final assessment of the project**

- 29
30 () Excellent
31 (x) Very good
32 () Very good, but mild issues should be addressed
33 () Good
34 () Good, but it has limitations to be addressed
35 () Fair
36 () Seriously limited
37
38
39

40 **Please analyze the budget, considering the following:**

41
42 **Permanent material and equipment (>R\$20.000,00) are justified**

- 43
44 (x) Yes
45 () No
46
47
48

49 **The rationale of the proposal is adequate**

- 50
51 (x) Yes
52 () No
53
54
55

56 **Materials and equipment needed that FAPESP should and must request a**
57 **partnership with third parties**

58
59 Not applicable
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4 **Request for consumption items is adequate**
5

6 The consumption items are crucial for development of the project.
7

8
9 **Services and materials that needed to be requested from third parties**
10

11 Not applicable
12

13 **Services that should be provided by the institution of the study upon FAPESP**
14 **request**
15

16 Not applicable
17

18
19 **Please provide, if any, value suggestions to be replace in the project in the following**
20 **items:**
21

22 **National permanent items**
23

24 None to report
25

26 **International permanent items**
27

28 None to report
29

30 **National consumption items**
31

32 As stated above, applicant requested implants
33

34 **Third parties services**
35

36 None to report
37

38 **International services**
39

40 None to report
41

42 **National transportation**
43

44 None to report
45

46 **International transportation**
47

48 None to report
49

50 **National daily expenses**
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52 None to report
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54 **International daily expenses**
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56 None to report
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5 **National miscellaneous expenses**
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8 None to report
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10 **International miscellaneous expenses**
11

12 None to report
13

14 **Total funding requested in national currency**
15

16 Adequate
17

18 **Total funding requested in international currency**
19

20 Adequate
21

22 **Sponsorship – considering the analyses above, please suggest number of technical training, if any**
23

24 Technical training I (TT-I)
25

26 Technical training II (TT-II)
27

28 Technical training III (TT-III)
29

30 Technical training IV (TT-IV)
31

32 Technical training IVa (TT-IVa)
33

34 Technical training V (TT-V)
35

36 **Final assessment of the budget**
37

38 (x) Adequate
39

40 () Adequate, but the suggestions above should be addressed
41

42 () Inadequate
43

44 **Check inadequacies observed, if any, on the following items:**
45

46 **Applicant's academic experience**
47

48 () Inadequate scientific/technological production for the development of the project
49

50 () Limited scientific/technological production
51

52 () Applicant lacks experience in the area of the project
53

54 **Research project**
55

56 () Objective of the project is unclear
57

58 () Objective of the project if limited for the complete development of the project
59

60 () Project lacks originality
61

() Limited theoretical framework/methodology
62

() Amount of work inadequate for the funding requested
63

() Project execution is questionable
64

() High cost considering the scientific relevance to the area
65

() Project's deadline is unrealistic

Budget proposal

() Total of items requested is unclear

() Overestimated budget

Other limitations, if any:

None to report

Statements related to the grant:

None to report

Detailed budget

Consumption item – National

Item	Description	Requested Amount (R\$)	Dispatched Amount (R\$)
1	140 units – 5.0 FASTIN RC ANCHOR with ORThOCORd (#222993) - Johnson & Johnson	135,520.00	121,968.00

Consumption item – National

Not applicable

Technical reserve – complementary benefits

Recipients	Responsible researcher (June 1, 2019 – May 31, 2021)
Currency	R\$
Value (unit) - annual	8,000.00
Date	May 25, 2019
Amount of complementary benefits	R\$16,000.00

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Title: Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	03
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	05
Protocol version	#3	Date and version identifier	17
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	18;19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	01
Roles and responsibilities: sponsor and funder	#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	06
Roles and responsibilities:	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee,	05

1	committees		data management team, and other individuals or groups	
2			overseeing the trial, if applicable (see Item 21a for data	
3			monitoring committee)	
4				
5	Introduction			
6				
7				
8	Background and	#6a	Description of research question and justification for	3;4;5
9	rationale		undertaking the trial, including summary of relevant studies	
10			(published and unpublished) examining benefits and harms for	
11			each intervention	
12				
13				
14	Background and	#6b	Explanation for choice of comparators	3;4;5
15	rationale: choice of			
16	comparators			
17				
18				
19	Objectives	#7	Specific objectives or hypotheses	5
20				
21				
22	Trial design	#8	Description of trial design including type of trial (eg, parallel	5
23			group, crossover, factorial, single group), allocation ratio, and	
24			framework (eg, superiority, equivalence, non-inferiority,	
25			exploratory)	
26				
27				
28				
29	Methods:			
30	Participants,			
31	interventions, and			
32	outcomes			
33				
34				
35				
36	Study setting	#9	Description of study settings (eg, community clinic, academic	5;6
37			hospital) and list of countries where data will be collected.	
38			Reference to where list of study sites can be obtained	
39				
40				
41	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	6;7
42			eligibility criteria for study centres and individuals who will	
43			perform the interventions (eg, surgeons, psychotherapists)	
44				
45				
46	Interventions:	#11a	Interventions for each group with sufficient detail to allow	8;9
47	description		replication, including how and when they will be administered	
48				
49				
50	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions	12
51	modifications		for a given trial participant (eg, drug dose change in response to	
52			harms, participant request, or improving / worsening disease)	
53				
54				
55	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and	10;11
56	adherence		any procedures for monitoring adherence (eg, drug tablet return;	
57			laboratory tests)	
58				
59				
60				

1	Interventions:	#11d	Relevant concomitant care and interventions that are permitted	NA
2	concomitant care		or prohibited during the trial	
3				
4				
5	Outcomes	#12	Primary, secondary, and other outcomes, including the specific	10;11;12
6			measurement variable (eg, systolic blood pressure), analysis	
7			metric (eg, change from baseline, final value, time to event),	
8			method of aggregation (eg, median, proportion), and time point	
9			for each outcome. Explanation of the clinical relevance of	
10			chosen efficacy and harm outcomes is strongly recommended	
11				
12				
13				
14	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-	13
15			ins and washouts), assessments, and visits for participants. A	
16			schematic diagram is highly recommended (see Figure)	
17				
18				
19				
20	Sample size	#14	Estimated number of participants needed to achieve study	6
21			objectives and how it was determined, including clinical and	
22			statistical assumptions supporting any sample size calculations	
23				
24				
25	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach	8
26			target sample size	
27				
28				
29	Methods: Assignment			
30	of interventions (for			
31	controlled trials)			
32				
33				
34	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, computer-	7;8
35	generation		generated random numbers), and list of any factors for	
36			stratification. To reduce predictability of a random sequence,	
37			details of any planned restriction (eg, blocking) should be	
38			provided in a separate document that is unavailable to those who	
39			enrol participants or assign interventions	
40				
41				
42				
43				
44	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, central	7;8
45	concealment		telephone; sequentially numbered, opaque, sealed envelopes),	
46	mechanism		describing any steps to conceal the sequence until interventions	
47			are assigned	
48				
49				
50				
51	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	7;8
52	implementation		participants, and who will assign participants to interventions	
53				
54				
55	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial	8
56			participants, care providers, outcome assessors, data analysts),	
57			and how	
58				
59				
60				

1	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is permissible,	8
2	emergency unblinding		and procedure for revealing a participant's allocated intervention	
3			during the trial	
4				
5				
6	Methods: Data			
7	collection,			
8	management, and			
9	analysis			
10				
11				
12				
13	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and	10;11;12;13
14			other trial data, including any related processes to promote data	
15			quality (eg, duplicate measurements, training of assessors) and a	
16			description of study instruments (eg, questionnaires, laboratory	
17			tests) along with their reliability and validity, if known.	
18			Reference to where data collection forms can be found, if not in	
19			the protocol	
20				
21	Data collection plan:	#18b	Plans to promote participant retention and complete follow-up,	10;11;12;13
22	retention		including list of any outcome data to be collected for	
23			participants who discontinue or deviate from intervention	
24			protocols	
25				
26				
27				
28				
29				
30				
31	Data management	#19	Plans for data entry, coding, security, and storage, including any	10;11
32			related processes to promote data quality (eg, double data entry;	
33			range checks for data values). Reference to where details of data	
34			management procedures can be found, if not in the protocol	
35				
36				
37				
38	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	14
39			outcomes. Reference to where other details of the statistical	
40			analysis plan can be found, if not in the protocol	
41				
42				
43	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and adjusted	14
44	analyses		analyses)	
45				
46				
47	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	14
48	population and missing		adherence (eg, as randomised analysis), and any statistical	
49	data		methods to handle missing data (eg, multiple imputation)	
50				
51				
52	Methods: Monitoring			
53				
54				
55	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary of	20
56	formal committee		its role and reporting structure; statement of whether it is	
57			independent from the sponsor and competing interests; and	
58				
59				
60				

1		reference to where further details about its charter can be found,	
2		if not in the protocol. Alternatively, an explanation of why a	
3		DMC is not needed	
4			
5	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	20
6	interim analysis	including who will have access to these interim results and make	
7		the final decision to terminate the trial	
8			
9			
10			
11	Harms	#22 Plans for collecting, assessing, reporting, and managing solicited	12
12		and spontaneously reported adverse events and other unintended	
13		effects of trial interventions or trial conduct	
14			
15			
16	Auditing	#23 Frequency and procedures for auditing trial conduct, if any, and	NA
17		whether the process will be independent from investigators and	
18		the sponsor	
19			
20			
21	Ethics and		
22	dissemination		
23			
24			
25	Research ethics	#24 Plans for seeking research ethics committee / institutional	5
26	approval	review board (REC / IRB) approval	
27			
28			
29	Protocol amendments	#25 Plans for communicating important protocol modifications (eg,	6
30		changes to eligibility criteria, outcomes, analyses) to relevant	
31		parties (eg, investigators, REC / IRBs, trial participants, trial	
32		registries, journals, regulators)	
33			
34			
35			
36	Consent or assent	#26a Who will obtain informed consent or assent from potential trial	7
37		participants or authorised surrogates, and how (see Item 32)	
38			
39			
40	Consent or assent:	#26b Additional consent provisions for collection and use of	NA
41	ancillary studies	participant data and biological specimens in ancillary studies, if	
42		applicable	
43			
44			
45	Confidentiality	#27 How personal information about potential and enrolled	10;12
46		participants will be collected, shared, and maintained in order to	
47		protect confidentiality before, during, and after the trial	
48			
49			
50	Declaration of interests	#28 Financial and other competing interests for principal	19
51		investigators for the overall trial and each study site	
52			
53			
54	Data access	#29 Statement of who will have access to the final trial dataset, and	19
55		disclosure of contractual agreements that limit such access for	
56		investigators	
57			
58			
59			
60			

1	Ancillary and post trial	#30	Provisions, if any, for ancillary and post-trial care, and for	16
2	care		compensation to those who suffer harm from trial participation	
3				
4				
5	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial results	20
6	trial results		to participants, healthcare professionals, the public, and other	
7			relevant groups (eg, via publication, reporting in results	
8			databases, or other data sharing arrangements), including any	
9			publication restrictions	
10				
11				
12				
13	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	19;20
14	authorship		professional writers	
15				
16				
17	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	20
18	reproducible research		participant-level dataset, and statistical code	
19				
20				
21	Appendices			
22				
23	Informed consent	#32	Model consent form and other related documentation given to	25;26;27;28
24	materials		participants and authorised surrogates	
25				
26				
27	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	NA
28			biological specimens for genetic or molecular analysis in the	
29			current trial and for future use in ancillary studies, if applicable	
30				
31				

Notes:

- 34
- 35 • 18a: 10;11;12;13
- 36
- 37 • 18b: 10;11;12;13
- 38
- 39 • 32: 25;26;27;28 The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution
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- 41 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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BMJ Open

Clinical Outcomes and Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-043126.R1
Article Type:	Protocol
Date Submitted by the Author:	15-Oct-2020
Complete List of Authors:	Pierami, Rafael; Hospital Israelita Albert Einstein, Sistema Locomotor; Grupo de Ombro e Cotovelo do Hospital Alvorara Moema, Departamento de Ortopedia Lenza, Mario; Hospital Israelita Albert Einstein, Programa Locomotor Antonioli, Eliane; Hospital Israelita Albert Einstein, Orthopaedic Oliveira, Isadora; Hospital Israelita Albert Einstein, Sistema Locomotor Castro, Isabela; Hospital Israelita Albert Einstein, Sistema Locomotor Manente, Felipe; Hospital Israelita Albert Einstein, Sistema Locomotor Fairbanks, Paula; Hospital Israelita Albert Einstein, Sistema Locomotor Carrera, Eduardo; Hospital Israelita Albert Einstein, Departamento de Ortopedia Matsumura, Bruno; Hospital Israelita Albert Einstein, Departamento de Ortopedia
Primary Subject Heading:	Health economics
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY, Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Orthopaedic sports trauma < ORTHOPAEDIC & TRAUMA SURGERY

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1
2
3 1 **1. Title:** Clinical Outcomes and Cost-Utility of Rotator Cuff Repair Surgery by Open and
4
5 2 Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial
6
7

8 3 **1a. Short title:** Cost-utility of open and arthroscopic rotator cuff repair
9

10
11 4 **1b. Authors:** Rafael Pierami¹, Eliane Antonioli², Isadora Oliveira², Isabela Queirós Castro², Felipe
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13 5 Manente³, Paula Fairbanks³, Eduardo da Frota Carrera¹, Bruno Akio Matsumura¹, Mário Lenza²
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38 15 **1e. Trial Sponsor:** Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP
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22 2. Abstract

23 Introduction: Rotator cuff injuries account for up to 70% of pain in the shoulder. However,
24 there is still no consensus on the best surgical treatment of patients with rotator cuff injuries,
25 regarding the cost-effectiveness and cost-utility analysis between the open and arthroscopic
26 methods of rotator cuff repair. The objective of this trial is to compare the efficacy, cost-
27 effectiveness and cost-utility of open and arthroscopic procedure for rotator cuff repair.

28 Methods and Analysis: The trial is a two-group, parallel design, randomized controlled
29 trial. A total of 100 patients with symptomatic rotator cuff lesion will be allocated in either open
30 or arthroscopic technique in a 1:1 ratio, considering smoking (yes or no), lesion size (less than 3
31 cm or more than 3 cm) and diabetes (present or absent) as stratification factors. All patients will
32 be included in the same rehabilitation program after the intervention. The primary outcomes
33 measure will be the Constant-Murley score and EuroQol 5-D-3L at 48 weeks post-surgery.
34 Secondary outcomes include cost-effectiveness, cost-utility, pain, complications and clinical
35 analysis, using the simple shoulder test (SST), Visual Analogue Pain Scale (VAS), integrity of the
36 repair evaluated through magnetic resonance imaging, complications and failures of the proposed
37 methods. For the cost-effectiveness analyses, we will use the VAS and the Constant-Murley Score
38 as measures of effectiveness; for the cost-utility analyses, we will use the EuroQol- 5D-3L as a
39 measure of utility in terms of incremental cost per quality-adjusted life-years (QALY).

40 Ethics and Dissemination: The study has been approved by the local Research Ethics
41 Committee from both institutions: Hospital Israelita Albert Einstein and Hospital Alvorada
42 Moema/ Hospital Pró-Cardíaco. The results will be published in a peer-review open access journal.

43 Trial Registration Number: NCT04146987

1
2
3 44 Keywords: rotator cuff; surgery; arthroscopy; open repair; cost-effectiveness; QALY
4
5

6 45 **Strengths and limitations of this study**
7

- 8
9 46 • This study is a prospective, randomized trial, that is the best design to address the study
10
11 47 question. Its methodological analyses is the best option to determine cost-utility and will
12
13 48 provide a strong evidence.
14
15
16 49 • It will provide surgeons and healthcare providers with important information about the
17
18 50 surgical technique and the cost-effectiveness and cost-utility of these techniques
19
20
21 51 • This study will provide important information about rotator cuff healing, what is still not
22
23 52 certain
24
25 53 • The lack of blinding of the patient and surgeons is a limitation to the study design
26
27
28

29 54 **3. Introduction**
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31
32

33 55 **3a. Background and Rationale**
34
35

36 56 Musculoskeletal injuries are a major cost to the healthcare system. North American data
37
38 57 estimate that approximately 4.5 million patients annually seek medical attention due to shoulder
39
40 58 pain; of these, two million have some symptoms related to the rotator cuff. About 250,000 rotator
41
42 59 cuff repair surgeries are performed annually in the United States of America (US), and with the
43
44 60 continued increase in life expectancy and aging, there is a tendency to increase this
45
46 61 number[1][2][3]. An evaluation of the primary health care system in Cambridge, United Kingdom,
47
48 62 showed that the average frequency of shoulder pain was 9.5 per 1,000 individuals [4]. Of these,
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50 63 86% had rotator cuff tendinopathy.
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3 64 The rotator cuff is a group of four muscles and their tendons that act to stabilize the
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5 65 shoulder and allow for its extensive range of motion. Four muscles and their attached tendons
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7
8 66 make up the rotator cuff: the subscapularis, supraspinatus, infraspinatus, and teres minor. The long
9
10 67 portion of the biceps tendon also contributes to cuff function, which is to stabilize the humeral
11
12 68 head in the glenoid cavity, preventing superior migration of the humeral head [5].
13
14

15 69 The possible lesions range from tendon degeneration (tendinosis/tendinopathy), through
16
17 70 partial tear (articular, interstitial or bursal), to complete tear. Its etiology is multifactorial and the
18
19 71 main factors associated with tears are tendon degeneration related to aging, trauma, tendon
20
21 72 insertion hypovascularity and genetic factors[6][7][8]. Since most lesions are caused by wear and
22
23 73 degeneration related to aging, people over 40 years are at great risk[3]. Diagnosis is made by
24
25 74 associating history and physical examination along with imaging methods, and magnetic
26
27 75 resonance imaging (MRI) is considered the method of choice [9]–[17].
28
29
30
31

32 76 Treatment of rotator cuff lesion depends on the type of tear, the patient's functional
33
34 77 capacity, age, and the presence of symptoms. In general, tendon degeneration and partial tears are
35
36 78 treated non-surgically, with physiotherapy, injections and analgesic medications. Complete and
37
38 79 incomplete tears that did not respond well to conservative treatment, however, might be treated
40
41 80 surgically [12], [18]–[20][3][21][22].
42
43

44 81 Among the surgical options, the open method is still considered the gold standard, with
45
46 82 good or excellent results in over 90% of cases [23]–[25]. Due to arthroscopy and the evolution of
47
48 83 arthroscopic instruments and implants in the last two decades, the arthroscopic repair technique
49
50 84 has gained space and is widely used. Some studies [23]–[26] did not show superiority of one
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52 85 technique over another in terms of clinical outcomes. On the other hand, since the cost of
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3 86 arthroscopic surgery is supposedly higher, due to the required equipment, it is important to
4
5 87 establish which option has the best cost-utility ratio. Other published studies suggested that the
6
7
8 88 open method is superior than the arthroscopic method in relation to cost-utility [27]–[29]. To date,
9
10 89 no study in our country has assessed the comparison of the cost-utility of the two techniques;
11
12 90 considering that the open technique is being left behind, is important to determine if it remains a
13
14
15 91 viable, reliable and cost-effective option for the treatment of rotator cuff tears.

17 92 **3b. Objectives**

19
20
21 93 Despite the high incidence of rotator cuff tears, there is no consensus about the best method
22
23 94 of repair, neither which method has the best cost-effectiveness and cost-utility ratio. Therefore, the
24
25 95 present study aims to compare the open and arthroscopic methods for rotator cuff repair and
26
27 96 determine which presents the best cost-effectiveness ratio.

29 30 97 **4. Trial Design**

31
32
33 98 The trial will be a prospective randomized controlled clinical trial.

35 36 99 **5. Methods**

37
38
39 100 This randomized controlled trial will follow the Consolidated Standards of Reporting Trials
40
41 101 (CONSORT) Statement [30]; also the protocol was developed following the SPIRIT
42
43 102 guidelines[31]. It will be performed at Hospital Alvorada Moema (Shoulder and Elbow Surgery
44
45 103 Center of Excellence), São Paulo, Brazil. The cost analysis will be performed by Hospital Israelita
46
47 104 Albert Einstein team, São Paulo, Brazil. The project was approved by both hospitals research ethics
48
49
50
51 105 committee and registered in clinicaltrials.gov.

106 **5a. Sample size**

107 The sample size estimate was obtained to detect differences between the open and
108 arthroscopic repair groups in relation to the primary outcome of the study, Constant-Murley Score
109 (CM) instrument after the intervention. Kukkone's et al. 2013 study [32] estimated the clinically
110 important minimal difference in CM score in 10.4 points in patients with rotator cuff rupture after
111 3 months of surgical treatment by the arthroscopic method. The estimated sample size of 45
112 patients per group, total of 90 patients, would reach 90% power to detect a 10.4 difference between
113 the groups in the CM instrument post-operative score with a standard deviation of up to 15 points
114 with a significance level of 5% using a t-Student test. Predicting a loss of around 10% at 12 months
115 of follow-up we aim to recruit 50 patients per group (PASS software [33]).

116 **5b. Inclusion criteria**

117 All patients eighteen years of age or older, presenting with complete rotator cuff tear or a
118 partial rotator cuff tear of at least 50% of tendon thickness, with symptoms (pain and/or weakness),
119 where conservative therapy failed will be included. The tendon tear will be confirmed by a
120 Magnetic Resonance Imaging (MRI).

121 **5c. Exclusion criteria**

122 Patients with previous shoulder surgery, previous fractures in the affected shoulder, those
123 with passive range of motion limitation (joint stiffness with an elevation of 90 degrees or less),
124 radiographic signs of glenohumeral osteoarthritis or neurologic injury will be excluded. Patients
125 will also be excluded if they do not wish to participate or are unable to understand or sign the

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2
3 126 informed consent form (due to conditions such as cognitive impairment, or mental illness) or if
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5 127 there are any medical conditions that contraindicate any of the surgical methods.
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9 128 **5d. Randomization and allocation**

11
12 129 After eligibility assessment, all patients will be informed about the nature and purpose of
13
14 130 the study and will only be included after agreeing with the study and signing the informed consent
15
16 131 form, that will be obtained by the surgeon that evaluated the patient and indicated the surgery.
17
18 132 Patients will be consecutively allocated to one of two proposed treatment methods: open rotator
19
20 133 cuff repair or arthroscopic rotator cuff repair. The software R was used to generate a randomization
21
22 134 list, considering 100 patients to be included in the study and the same probability of allocation for
23
24 135 both methods of surgery (open and arthroscopic repair). A stratified randomization will be
25
26 136 performed using the following variables (strata): smoking (yes or no), the size of the lesion (≤ 3
27
28 137 cm or > 3 cm) and diabetes (present or absent). Randomization will be performed by the REDCap
29
30 138 platform (Research Electronic Data Capture – Vanderbilt University)[34][35] after the patient is
31
32 139 anesthetized and prepared for the surgery. A person not associated with the study will open the
33
34 140 software and acquire one of the two techniques possible and tell the surgeon who will perform the
35
36 141 surgery.
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43 142 **5e. Recruitment**

44
45 143 All patients that already would be treated by the shoulder surgeons at Hospital Alvorada
46
47 144 Moema (Shoulder and Elbow Surgery Center of Excellence), São Paulo, Brazil, will be enrolled
48
49 145 in this trial.
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146 **5f. Blinding**

147 Due to the type of interventions, neither participants nor treatment providers can be blinded
148 to treatment allocation. The outcome assessment of the primary and secondary outcomes
149 (Constant-Murley; EuroQol; VAS and SST), patient-reported outcomes, will not be blind. One of
150 the authors (RP) will assess all other clinical outcomes. The statisticians conducting the analyses
151 will be blinded to the treatment status until the analyses are completed.

152 **5g. Ethics and Dissemination**

153 This study was developed and will follow the International Conference Guideline for Good
154 Clinical Practice (ICH GP) to assure that the data and results are credible and that the rights,
155 integrity and confidentiality of the trial subjects are protected and respected[36][37].

156 All authors agreed to publish the results of the present study in a peer-reviewed open access
157 journal, despite the results and conclusions found. All data will be available upon request.

158 **5h. Patient and Public Involvement**

159 The patients nor the public were involved on the design and development of this study.
160 Their participation will first occur with the contact between the surgeon and patient, time which
161 they will be informed about the study and will decide to participate or not. At this time, they will
162 be informed about the purpose and importance of it. At all times during the follow-up the patients
163 will be able to enquiry the researchers and surgeons about the project and to make suggestions and
164 complaints about it.

165 All the outcomes measures will be self-reported. In case of doubts from the patients, they
166 will be assisted by one member of the research team.

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3 167 Since the authors agreed to publish the results of this research, patients will not be involved
4
5 168 on the dissemination. However, they will be encouraged to disseminate the knowledge among the
6
7
8 169 community.
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10 11 170 **6. Intervention methods**

12
13
14 171 Five surgeons with at least four years of surgical technique experience will participate in
15
16 172 this study (EFC, MTCA, RP, BAM, VR). Also, the residents of shoulder and elbow surgery, as
17
18
19 173 well as the residents of Orthopedics and Traumatology from Hospital Alvorada Moema and
20
21 174 residents in shoulder and elbow surgery at Albert Einstein Hospital may participate in surgeries.
22

23
24 175 Open surgery: patients will be positioned in a beach chair position with the affected limb
25
26 176 pending off the table, allowing manipulation and full range of motion. After standard patient
27
28
29 177 preparation, an anterolateral incision will be made in the shoulder; the deltoid muscle belly will be
30
31 178 gently divided along its fibers until exposure of the subdeltoid / subacromial bursa, which will be
32
33 179 partially excised for exposure of the subacromial space and rotator cuff tendons. After mobilization
34
35
36 180 and release of the ruptured tendons and debridement of the rotator cuff footprint, the tendon repair
37
38 181 to the bone will be performed using 5.5mm metal anchors (“Super Revo”-CONMED, USA),
39
40 182 according to the preference and technique chosen by the surgeon. In all cases, the release of the
41
42
43 183 coracoacromial ligament and acromioplasty will be performed.
44

45
46 184 Arthroscopic Technique: the patients will be positioned in lateral decubitus position, with
47
48 185 the limb to be operated attached to a skin traction device, which through a traction post and 7
49
50 186 kilograms (kg), will maintain the shoulder in the following position: abduction of 30 to 60 degrees
51
52
53 187 and flexion of 20 to 30 degrees. After standard patient preparation, a posterolateral incision will
54
55 188 be made in the shoulder for optic introduction, with a 50mmHg pressure pump and a 0.90 flow,
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3 189 and inspection of the glenohumeral joint. After establishment of all required arthroscopic portals,
4
5 190 joint inspection will be performed and any, if present, associated pathologies will be addressed.
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7
8 191 With the use of shaver blades, partial bursectomy will be performed and any adherence to the
9
10 192 tendon stumps will be released, as well as debridement of the rotator cuff footprint. The tendon
11
12 193 will then be reinserted to the bone using metallic 5.5mm anchors (“Super Revo”-CONMED,
13
14 194 USA), according to the preference of each surgeon. The technique used, as well as the suture
15
16 195 configuration and type of knot used, will be defined by the surgeon, according to his preference .
17
18
19 196 After tendon repair, the coracoacromial ligament will be released, as well as acromioplasty will be
20
21
22 197 performed.

23 24 198 **7. Postoperative rehabilitation**

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26
27 199 All patients will undergo the same postoperative rehabilitation protocol: use of Velpeau
28
29 200 sling for 6 weeks; pendulum exercises from the second week; active movement and recovery of
30
31 201 the range of motion from the sixth week and strengthening from the twelfth week.
32
33
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35 202 The patients will be oriented to perform home exercises and, as well, to be assisted by a
36
37 203 physiotherapist twice a week from the sixth week of surgery and on. It is expected at the end of
38
39 204 treatment the need of about thirty sessions of physical therapy.
40
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42

43 205 **8. Outcomes assessment**

44
45 206 Study data will be collected and managed using REDCap (Research Electronic Data
46
47 207 Capture- “Vanderbilt University, Nashville, Tennessee, USA”) hosted at Hospital Israelita Albert
48
49 208 Einstein [34][35]. REDCap is a secure, web-based software platform designed to support data
50
51 209 capture for research studies, providing: 1) an intuitive interface for validated data capture; 2) audit
52
53 210 trails for tracking data manipulation and export procedures; 3) automated export procedures for
54
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1
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3 211 seamless data downloads to common statistical packages; and 4) procedures for data integration
4
5 212 and interoperability with external sources.
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7

8 213 All study participants will be evaluated preoperatively, at the hospital discharge and 1, 2,
9
10 214 6, 24 and 48 weeks after the intervention. The Constant-Murley score, Visual Analogue Scale,
11
12 215 EuroQol-5D-3L and the Simple Shoulder Test questionnaires will be filled out by the patient and
13
14 216 assessed by evaluators to the assigned intervention. The endpoint of cost-utility analysis will be
15
16 217 48 weeks; clinical outcomes will also be assessed at 6 and 24 weeks.
17
18
19

20 218 To prevent loss of follow-up all the patients will be monitored by REDCap software and
21
22 219 alerts will be sent to each patient near time points defined by the investigators. One week before
23
24 220 every medical consultation and at the twelfth week, regarding the rehabilitation process. If the
25
26 221 patient fails to fill any questionnaire or does not attend the medical consultations, he will be
27
28 222 contacted by phone and e-mail. If the patient became incommunicable, we will consider a lost
29
30 223 follow-up scenario, where, in accordance with the intention to treat principle, appropriate statistical
31
32 224 methods for data analysis, that consider unbalanced data and loss of follow-up, such as Generalized
33
34 225 Estimating Equation Model (GEE), will consider all patients observations, even if they fail in some
35
36 226 moment. Thereby, these patients will not be excluded, and all data will be considered.
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42 227 **9. Primary outcome**

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45 228 The Brazilian Portuguese Version of the Constant-Murley Score (CM) [38] will be
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47 229 measured preoperatively at 6, 24 and 48 weeks after the intervention. Research assistants (not
48
49 230 blinded to the study aim) will ask the patients to fill in the validated CM form for the Portuguese
50
51 231 language and measure the range of motion with an analogic goniometer. The CM scale covers
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232 different domains of shoulder function (pain, activities of daily living, range of motion and power),
233 punctuating each of them; it ranges from 0 to 100, with higher scores indicating better function[38].

234 EuroQol-5D-3L (European Quality of Life), a generic score developed to describe health-
235 related quality of life [30] will also be assessed preoperatively, at 6, 24 and 48 weeks
236 postoperatively. This score includes five health domains: mobility, self-care, usual activities,
237 pain/discomfort, and anxiety/depression; each domain has 3 levels: no problem; some problems
238 and extreme problems. In addition, the EuroQol-5D-3L has a visual analog scale where the
239 participant assigns a value between 0 and 100 to his or her own health condition, where 100 means
240 “the best imaginable health status” or “the best health state you can imagine” and 0 means “the
241 worst imaginable health state” or “the worst health state you can imagine”. This is used to obtain
242 a respondent’s stated preference values, not to record their own health state. [39]. At the end of
243 its application, EuroQol-5D-3L will provide a unique numerical value that can be used for
244 longitudinal comparison between different time periods.

245 **9b. Secondary outcomes**

246 Clinical outcomes will also be assessed by the Simple Shoulder Test (SST), validated for
247 Portuguese [40], preoperatively and at 6, 24 and 48 weeks after the procedure. SST is a simple,
248 quick and widely used questionnaire for shoulder function measurement; it consists of 12
249 dichotomous questions answered by the patient himself. Each positive answer (yes) is given a
250 score; at the end of the questionnaire the percentage of positive answers (score) is made, and the
251 higher the percentage, the better the shoulder function. Other outcomes measured will be VAS
252 (visual analogue pain scale) at hospital discharge, 1, 2, 6, 24 and 48 weeks after the intervention.
253 This scale allows pain intensity to be measured with maximum interobserver reproducibility; it

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2
3 254 consists of a 10 cm straight line with the ends determining the limits of pain sensation (no pain;
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5 255 worst pain ever experienced); the distance between zero (no pain) and the patient's demarcation
6
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8 256 defines the intensity of pain[41].
9

10
11 257 Complications and failures of the proposed methods will also be assessed. Failures will be
12
13 258 characterized as the need for additional surgical procedures and/or change of the initially proposed
14
15 259 procedure. Patients who, for any reason, demonstrate treatment failure or require additional
16
17 260 interventions will be followed up and their results included in the group in which they were initially
18
19
20 261 randomized, according to the intention to treat principle.
21
22

23 262 At the final follow-up (forty-eight weeks), the integrity and healing of repaired rotator cuff
24
25 263 will be assessed through Magnetic Resonance Imaging (MRI).
26
27

28 264 **9c. Cost-effectiveness**

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31 265 Cost-effectiveness and cost-utility analyses will be assessed by the estimate of direct and
32
33 266 indirect costs to the private healthcare system at 48 weeks. The perspective adopted in the study
34
35 267 will be the social costs, the direct and indirect medical costs. The set timeframe will be 48 weeks
36
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38 268 and a sensitivity analysis will be performed with the costs data, considering 0% to 5% discount
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40 269 rate to define the optimal discount rate for the data, according to methodological Guidelines for
41
42 270 Economic Evaluation of Health Technologies – Brazilian Ministry of Health[42], [43][44]. The
43
44 271 costs included in direct medical costs will be: hospitalization, costs related to arthroscopic
45
46 272 instruments (e.g. cannulas, shaver blades, suture passer, ablator) medical fees, medication; the
47
48
49 273 indirect costs: costs of absence from work, which will be estimated by the patient-reported number
50
51 274 of days away from work multiplied by the average wage rate of the current year. The costs will be
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54 275 converted from Brazilian Reais to US dollars and brought to the cost schedule of the current year,
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56

276 in order to avoid that the effect of inflation on the medical inputs influences the analysis. For the
 277 cost-effectiveness analyses, the VAS and the CM will be used as measures of effectiveness. For
 278 the cost-utility analyses, the EuroQOL-5D-3L will be used as a measure of utility. The timetable
 279 of outcomes assessment is described on Table 1.

280 **Table 1.** Timetable of assessment

STUDY PERIOD								
	Enrolment	Allocation	Post-Allocation				Close-Out	
TIMEPOINT	0	0	Surge ry	1w	2w	6w	24 w	48w
ENROLMENT :								
Eligibility	X							
Screen	X							
Informed Consent	X							
CM; EQ-5D, SST; VAS Allocation		X						
INTERVENTIONS								
Open Repair			X					
Arthroscopic Repair			X					
ASSESSMENTS :								
CM; EQ-5D, SST; VAS						X	X	X
MRI	X							X
Complications			X	X	X	X	X	X
Economics			X	X	X	X	X	X

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4
56 282 **10. Data analysis**
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8

9 283 The descriptive analyzes of variables will be based on the absolute frequencies and
10
11 284 percentages for categorical variables and summary measures as means and standard deviations or
12
13 285 medians and quartiles, as well as minimum and maximum values for numerical variables [45].
14
15
16 286 Clinical scores will be represented by individual profile graphs separately by the surgical technique
17
18 287 group.

19
20
21 288 The groups will be compared according to the presence of categorical clinical outcomes
22
23 289 (failures, complications and healing integrity) by Chi-square or Fisher's exact tests, depending on
24
25
26 290 the distribution observed after data collection.

27
28
29 291 For inferential analysis of continuous variables clinical outcomes, mixed models will be
30
31 292 used and, if the normal distribution is not adequate, generalized mixed models will be used [46].
32
33 293 The models will have time effects (preoperative, 6, 24 and 48 weeks after intervention), surgical
34
35 294 technique group (open repair or arthroscopic repair) and the interaction effect between time and
36
37
38 295 group. The size of the lesion (smaller than three cm or larger than three cm) will also be included
39
40 296 in the models as a control variable, seeking to avoid possible biases.

41
42
43 297 The analyzes will be performed with the aid of the SPSS program (SPSS Inc., Chicago,
44
45 298 Illinois, USA) [47], considering a significance level of 5%.

46
47
48 299 **11. Safety**
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50
51 300 There will be no benefit to the participant, beyond what is expected for the correction of
52
53 301 the rotator cuff tear, expecting an improvement of pain and function of the affected shoulder. The
54
55 302 risks of the present study are those inherent in any surgical treatment and anesthetic procedure,

1.

1
2
3 303 such as surgical wound infection, scar formation, pain, decrease in shoulder range of motion,
4
5 304 rotator cuff tear, neurovascular injury. If any complications occur, all patients will be treated by
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7
8 305 the same surgical team until the complication is healed.
9

10
11 306 Both surgical techniques have the same goal, that is, to repair the ruptured tendon to the
12
13 307 bone. The open technique requires a larger incision, as well as greater surgical dissection and
14
15 308 manipulation of the deltoid muscle, which may cause greater postoperative pain and weakness of
16
17 309 this muscle, in addition to causing a slightly larger scar. However, it provides great visualization
18
19
20 310 and manipulation and mobilization capability of the ruptured tendon, which provides a safer and
21
22 311 tension-free repair.
23
24

25 312 The arthroscopic technique is performed with some point-shaped cuts in the shoulder,
26
27 313 usually three or four; due to smaller incisions, it requires less muscle manipulation, which
28
29
30 314 theoretically would cause less postoperative pain and less muscle weakness of the deltoid muscle,
31
32 315 it also has minor scars. However, this technique requires more surgeon's experience and the
33
34 316 mobilization of the ruptured tendon(s) is limited. Using a large amount of saline may cause edema
35
36
37 317 in the operated shoulder, which is usually resolved after the first 12 hours of surgery.
38
39

40 318 Finally, there is a minimal risk of loss of data confidentiality; all data will managed, stored
41
42 319 and protected by REDCAP software[34], [35]. One of the researchers will have access to all data
43
44 320 during the entire trial period. Any adverse event will be reported to the researchers involved and
45
46
47 321 communicated to the main investigator according to the Institutional Review Boards description.
48

49 322 **12. Discussion**

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51
52 323 There is no consensus about the best cost-effectiveness of surgical treatment of patients
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55 324 with degenerative rotator cuff injuries. Several studies [27], [28], [48], [49] suggest that the open
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3 325 repair method is more cost-effective than the arthroscopic method, resulting in the same clinical
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5 326 outcome with lower cost. Adla, Deepthi N. et. al [27] in a prospective nonrandomized study,
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7 327 showed that both techniques lead to the same clinical outcomes. The costs of arthroscopic surgery
8
9 328 were higher than the open surgery, mainly due to the costs of the suture anchors, which was used
10
11 329 only in the arthroscopic group, is important to notice that in most of the open surgeries, the repair
12
13 330 was performed through transosseous sutures. Köse, Kamil Çağrı et. al [28], in a retrospective
14
15 331 study, also demonstrated similar clinical outcomes, although the costs of arthroscopic procedure
16
17 332 being much higher. Importantly, the open repair technique was performed using transosseous
18
19 333 sutures and the arthroscopic method using suture anchors and also, the open repair group required
20
21 334 longer length hospital stay. Hui, Yik Jing et. al [48] in a retrospective cohort study, described a
22
23 335 significantly higher cost for the arthroscopic procedure, compared to the open repair, evaluating
24
25 336 only the in-hospital costs, but with the same clinical outcomes. However, it is important to
26
27 337 emphasize that the open repair was performed using transosseous sutures, without suture anchors
28
29 338 and that the arthroscopic group needed a longer surgery time. Churchill, R.S. et. al [49] using the
30
31 339 New York Ambulatory Database System, with a total of 5,224 cuff repair surgeries, of which
32
33 340 1,334 open repair and 3,890 arthroscopic repair, showed that the mini-open rotator cuff repair costs
34
35 341 significantly less than the arthroscopic repair and requires significantly less surgical time.
36
37 342 However, no clinical outcomes have been analyzed in this study, making it impossible to determine
38
39 343 the cost-effectiveness ratio. An important study by Carr, A.J. et. al [50] carried out as a prospective
40
41 344 multicenter randomized clinical trial, concluded that there is no difference in the effectiveness and
42
43 345 cost-effectiveness between the open repair surgery and arthroscopic surgery after 24 months of
44
45 346 follow-up, even with the higher initial costs in the arthroscopy surgery. An economic evaluation
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47 347 of the data from this study was carried out, showing that the Incremental Cost Effectiveness (ICER)
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348 was uncertain and the arthroscopic repair surgery was slightly more costly and less effective than
349 open repair surgery.

350 Thus, despite the high incidence of rotator cuff tear, there is insufficient evidence to
351 determine the best method for treating these injuries. So, the present study proposes to answer the
352 clinical question of which method, open or arthroscopic, presents the best cost-utility in the
353 surgical treatment of rotator cuff tear. Providing conclusive, good quality evidence for and
354 contributing to the evidence base of methods used to treat rotator cuff injuries.

355 **13. Trial status**

356 Protocol Trial version: 4 Date: 10/06/2020

357 Recruitment Start Date: August/2020

358 Recruitment Estimated End Date: December/2021

359 Recruiting

360 **14. Additional files**

361 **Table 1.** Timetable of assessment

362 Informed Consent

363 **15. Abbreviations**

364 CONSORT: Consolidated standards of reporting trials; VAS: Visual analogue scale; MRI:
365 magnetic resonance imaging; QALY: quality-adjusted life years; CM: Constant-Murley Score;
366 SST: Simple Shoulder Test

367 **16. Declarations**

368 **16.1 Ethics Approval and Consent to Participate**

369 The study has been approved by the local Research Ethics Committee from both
370 institutions: Hospital Israelita Albert Einstein (CAAE 19182619.3.1001.0071) and Hospital
371 Alvorada Moema/ Hospital Pró-Cardíaco (CAAE 19182619.3.2002.5533). Digital, informed
372 consent to participate will be obtained from all participants through software REDCAP[35][34].

373 All and any modifications in this study will be promptly reported to all Research Ethics
374 Committee, all institutions, all investigators and all participants.

375 **16.2 Consent for Publication**

376 Not Applicable

377 **16.3 Availability of Data and Materials**

378 The datasets used and/or analyzed during the current study will be available from the
379 corresponding author upon request.

380 **16.4 Competing interests**

381 The authors declare that they have no competing interests.

382 **16.5 Funding**

383 This study is supported by Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP
384 2019/02159-3).

385 **16.6 Registry**

386 The project is registered in the clinicaltrials.gov database (NCT04146987
387 <https://clinicaltrials.gov/ct2/show/NCT04146987?term=NCT04146987&draw=2&rank=1>).

388 **16.7 Author contributions**

389 Mário Lenza (ML) is the Chief Investigator; he conceived the study, led the proposal and protocol
390 development. He helped write the first draft of the manuscript and project grant (sponsor)

391 Rafael Pierami (RP) is the lead trial methodologist and helped in the study conceiving and
392 development. He helped write the first draft of the manuscript and project grant (sponsor)

393 Eliane Antonioli (EA) contributed to study design and to development of the proposal. She He
394 helped write the first draft of the manuscript and project grant (sponsor)

395 Isadora Oliveira (IO) contributes to study design related to QALY and cost-utility design. She also
396 helped on the reviews and translation of the manuscript.

397 Isabel Queiros Castro (IQC) is responsible for cost analysis and cost-utility analysis. She also
398 helped on the methodological development

399 Felipe Manente (FM) helped in the English translation and registration/publication of the trial. He
400 also helped on the reviews and corrections of the manuscript.

401 Paula Fairbanks (PF) helped in the English translation and registration/publication of the trial. She
402 also helped on the reviews and corrections of the manuscript.

403 Eduardo da Frota Carrera (EFC) helped in the study conceiving and development; he also helped
404 on the manuscript corrections and reviews

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3 405 Bruno Akio Matsumura (BAM) helped in the study conceiving and development; he also helped
4
5 406 on the manuscript corrections and reviews
6
7

8 407 All authors read and approved the final manuscript.
9

10 11 408 **16.8 Acknowledgements** 12

13
14 409 Not applicable
15

16 17 410 **17. Dissemination policy** 18

19
20 411 All the authors are committed and agree to publish the full results of the research, despite the final
21
22 412 results.
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25 26 413 **18. Data Monitoring Committee (DMC)** 27

28 414 Since this trial have a short duration and both surgical techniques have known minimal risks, there
29
30 415 is no need for such committee.
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33 34 416 **19. References** 35

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33 554 **TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO**

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38 556 ***Título do projeto:*** *Custo-Efetividade da Cirurgia de Reparo do Manguito Rotador Pelas Técnicas*
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41 557 *Aberta e Artroscópica. Ensaio Clínico Randomizado.*

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43 558 ***Pesquisadores responsáveis:*** *Mario Lenza e Rafael Pierami*

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47 560 O(a) Sr(a) está sendo convidado para participar, como voluntário, de uma pesquisa científica. O Termo de
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49 561 Consentimento Livre e Esclarecido tem por meta esclarecer esta pesquisa, explicando resumidamente seus
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51 562 objetivos, procedimentos, riscos e benefícios. Após ser esclarecido sobre as informações a seguir, e aceitar fazer
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53 563 parte do estudo, rubrique todas as páginas e assine ao final deste documento. Uma via será enviada para o(a) Sr(a)
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55 564 por e-mail.

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3 566 **Objetivo do estudo:**

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5 567 O objetivo deste estudo é avaliar o custo-efetividade (relação da melhora clínica com os custos dos
6 568 procedimentos) de dois tipos de cirurgias para o reparo do manguito rotador: cirurgia aberta e cirurgia artroscópica.

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9 570 **Descrição do estudo:**

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11 571 A ruptura do manguito rotador, ou seja, o rompimento dos tendões do ombro é a principal causa de dor no
12 572 ombro na população adulta, causando, além da dor, diminuição da força no ombro acometido e perda de qualidade
13 573 de vida, devido a dor constante e piora na qualidade do sono causado pela dor. Existem duas técnicas cirúrgicas para
14 574 correção desta doença: a técnica cirúrgica aberta, realizada por uma incisão (corte) no ombro e visualização direta
15 575 do tendão rompido; e a técnica cirúrgica artroscópica, realizada através de pequenos cortes no ombro, por onde são
16 576 introduzidos uma câmera de vídeo, para visualização do tendão rompido e instrumentais para realização da cirurgia.
17 577 Ainda não há uma definição se há diferença entre os resultados obtidos e as técnicas cirúrgicas utilizadas. O(a) Sr(a)
18 578 está sendo convidado para participar deste estudo pois há indicação de cirurgia para o reparo do manguito rotador.

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23 581 **Procedimentos a serem realizados:**

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25 582 O estudo terá dois grupos de pacientes: grupo que fará a reconstrução do manguito via técnica cirúrgica
26 583 aberta e o grupo que fará a reconstrução via técnica cirúrgica artroscópica. A seleção dos voluntários será feita de
27 584 forma randomizada, isto é, não saberemos em que tipo de cirurgia cada indivíduo será incluído. A duração total da
28 585 pesquisa será de um (01) ano e a participação do Sr(a) será em responder questionários sobre a sua saúde antes da
29 586 cirurgia, comparecer às consultas médicas, antes da cirurgia e após 6, 24 e 48 semanas da cirurgia e realizar os
30 587 exames de Ressonância magnética antes da cirurgia e após 48 semanas da cirurgia. Caso o(a) Sr(a) concorde em
31 588 fazer parte deste estudo, os dados preenchidos e coletados serão utilizados para fins de pesquisa. Importante
32 589 informar que os pacientes de ambos os tipos de cirurgia receberão os mesmos cuidados e os mesmos seguimentos
33 590 e que não serão necessários exames de imagem ou laboratoriais adicionais àqueles rotineiramente utilizados para
34 591 pacientes com lesão do manguito rotador. Como tratamento habitual após a cirurgia de lesão do manguito, o(a)
35 592 Sr(a) será orientado a realizar um programa de reabilitação que inclui o uso de tipóia do tipo Velpeau por seis (06)
36 593 semanas e um programa de exercícios pendulares orientados. Após, a tipóia será retirada e o(a) Sr(a) será orientado
37 594 a realizar exercícios domésticos para ganho de movimento, além de duas sessões semanais de fisioterapia para
38 595 analgesia e recuperação da amplitude de movimento do ombro. A partir da décima segunda semana (12ª) iniciarão
39 596 os exercícios de fortalecimento muscular sob orientação de fisioterapeuta. No término do estudo será verificado se
40 597 houve melhora na função do ombro, na qualidade de vida e na cicatrização do tendão reparado por meio de
41 598 questionários de simples preenchimento e exame de ressonância magnética.

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46 601 **Possíveis riscos e desconfortos:**

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48 602 Os riscos do presente estudo são aqueles inerentes a qualquer tratamento cirúrgico e procedimento
49 603 anestésico, como infecção da ferida operatória, formação de cicatriz, dor, limitação do arco de movimento do
50 604 ombro, rerruptura do manguito rotador, lesão neurovascular. A técnica cirúrgica aberta pode provocar maior dor
51 605 pós-operatória e fraqueza muscular, além de causar uma cicatriz pouco maior. A técnica cirúrgica artroscópica pode
52 606 causar menos dor pós-operatória e menos fraqueza muscular; além disso, apresenta cicatrizes menores, mas pode
53 607 causar edema no ombro operado, o que geralmente é revertido após as primeiras 12 horas da cirurgia.

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3 609 **Benefícios para o participante:**

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5 610 O(a) Sr(a) não terá benefício além do esperado para a operação de correção da lesão, esperando-se melhora
6 611 da dor e função do ombro operado, independente do tipo de técnica cirurgia utilizada. A sua participação ajudará a
7 612 entender qual das técnicas cirúrgicas apresenta o melhor custo-efetividade para o tratamento de lesão do manguito
8 613 rotador e permitirá apresentar à comunidade médica informações sobre a melhor indicação cirúrgica de tratamento.

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11 615 **Direitos do participante:**

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13 616 Sua participação é voluntária e o(a) Sr(a) pode retirar seu consentimento ou ainda descontinuar sua
14 617 participação em qualquer momento, se o assim o preferir, sem penalização e/ou prejuízo de qualquer natureza. Não
15 618 haverá nenhum custo ao Sr(a) proveniente deste estudo, assim como não haverá qualquer tipo de remuneração
16 619 pela sua participação.

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21 622 Estou ciente que:

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23 623 1. As informações obtidas serão analisadas em conjunto com as de outros voluntários, não sendo divulgada
24 624 a identificação de nenhum participante.

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27 626 2. As informações produzidas neste estudo serão mantidas em lugar seguro, codificadas e a identificação
28 627 só poderá ser realizada pela equipe do projeto.

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30 628
31 629 4. Em qualquer etapa do estudo, você terá acesso aos profissionais responsáveis pela pesquisa para
32 630 esclarecimento de eventuais dúvidas. O coordenador do projeto é o Dr. Mário Lenza e o principal responsável pelo
33 631 estudo é o Dr. Rafael Pierami. Os pesquisadores podem ser encontrados nos seguintes endereços: Dr. Mario Lenza
34 632 –Av. Albert Einstein, 627 – bloco A1 – 3º andar – Programa Locomotor, Morumbi, São Paulo – CEP 05652-900: Tel:
35 633 (11) 2151.1444; e-mail: mario.lenza@einstein.br; e Dr. Rafael Pierami –Avenida Ministro Gabriel Rezende de Passos,
36 634 550, 2º andar, Hospital Alvorada Moema – Centro de Excelência em Cirurgia de Ombro e Cotovelo, Moema, São
37 635 Paulo – CEP 04521-022 – Tel: (11) 2186-9810 ou (11) 2186-9809; e-mail: rafael.pierami@hotmail.com.

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41 637 Se você tiver qualquer dúvida ética em relação à pesquisa, entre em contato com:

42 638 **Comitê de Ética em Pesquisa do Hospital Israelita Albert Einstein** - Av. Albert Einstein 627/701, São
43 639 Paulo/SP, fone 2151-3729, e-mail: cep@einstein.br. Reclamações, elogios e sugestões deverão ser encaminhados
44 640 ao Sistema de Atendimento ao Cliente (SAC) por meio do telefone (11) 2151-0222 ou formulário identificado como
45 641 fale conosco disponível na página da pesquisa clínica ou pessoalmente.

46 642
47
48 643 **Comitê de Ética em Pesquisa em Seres Humanos do Hospital Pró-Cardíaco** (CEP/HPC) - Tel: (21) 3289-3802
49 644 - Localizado na Rua Voluntários da Pátria, 435/8º andar – Botafogo, Rio de Janeiro/RJ, CEP: 22270-005. Horário de
50 645 atendimento: de segunda à sexta-feira, das 09:00h às 16:00h.

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52 646
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54 647 Confirmando que li o conteúdo deste Termo de Consentimento Livre e Esclarecido e aceitei participar
55 648 voluntariamente deste estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a

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3 649 serem realizados, seus eventuais desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos
4 650 permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia do acesso a
5 651 tratamento hospitalar quando necessário. Concordo voluntariamente em participar deste estudo, sabendo que
6 652 poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou
7 653 prejuízos ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.
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Nome Completo do participante da pesquisa

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Data: __/__/__

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Assinatura do participante da pesquisa

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Nome completo e legível do pesquisador responsável

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Data: __/__/__

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Assinatura do pesquisador responsável

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18 681**Assinatura do representante legal**19
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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Title: Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	03
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	05
Protocol version	#3	Date and version identifier	17
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	18;19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	01
Roles and responsibilities: sponsor and funder	#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	06
Roles and responsibilities:	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee,	05

committees data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

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;4;5

Background and rationale: choice of comparators [#6b](#) Explanation for choice of comparators 3;4;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, non-inferiority, exploratory) 5

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 5;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: description [#11a](#) Interventions for each group with sufficient detail to allow replication, including how and when they will be administered 8;9

Interventions: modifications [#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) 12

Interventions: adherence [#11c](#) Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) 10;11

1	Interventions:	#11d	Relevant concomitant care and interventions that are permitted	NA
2	concomitant care		or prohibited during the trial	
3				
4				
5	Outcomes	#12	Primary, secondary, and other outcomes, including the specific	10;11;12
6			measurement variable (eg, systolic blood pressure), analysis	
7			metric (eg, change from baseline, final value, time to event),	
8			method of aggregation (eg, median, proportion), and time point	
9			for each outcome. Explanation of the clinical relevance of	
10			chosen efficacy and harm outcomes is strongly recommended	
11				
12				
13				
14	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-	13
15			ins and washouts), assessments, and visits for participants. A	
16			schematic diagram is highly recommended (see Figure)	
17				
18				
19				
20	Sample size	#14	Estimated number of participants needed to achieve study	6
21			objectives and how it was determined, including clinical and	
22			statistical assumptions supporting any sample size calculations	
23				
24				
25	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach	8
26			target sample size	
27				
28				
29	Methods: Assignment			
30	of interventions (for			
31	controlled trials)			
32				
33				
34	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, computer-	7;8
35	generation		generated random numbers), and list of any factors for	
36			stratification. To reduce predictability of a random sequence,	
37			details of any planned restriction (eg, blocking) should be	
38			provided in a separate document that is unavailable to those who	
39			enrol participants or assign interventions	
40				
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44	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, central	7;8
45	concealment		telephone; sequentially numbered, opaque, sealed envelopes),	
46	mechanism		describing any steps to conceal the sequence until interventions	
47			are assigned	
48				
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51	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	7;8
52	implementation		participants, and who will assign participants to interventions	
53				
54				
55	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial	8
56			participants, care providers, outcome assessors, data analysts),	
57			and how	
58				
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1	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is permissible,	8
2	emergency unblinding		and procedure for revealing a participant's allocated intervention	
3			during the trial	
4				
5				
6	Methods: Data			
7	collection,			
8	management, and			
9	analysis			
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12				
13	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and	10;11;12;13
14			other trial data, including any related processes to promote data	
15			quality (eg, duplicate measurements, training of assessors) and a	
16			description of study instruments (eg, questionnaires, laboratory	
17			tests) along with their reliability and validity, if known.	
18			Reference to where data collection forms can be found, if not in	
19			the protocol	
20				
21	Data collection plan:	#18b	Plans to promote participant retention and complete follow-up,	10;11;12;13
22	retention		including list of any outcome data to be collected for	
23			participants who discontinue or deviate from intervention	
24			protocols	
25				
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31	Data management	#19	Plans for data entry, coding, security, and storage, including any	10;11
32			related processes to promote data quality (eg, double data entry;	
33			range checks for data values). Reference to where details of data	
34			management procedures can be found, if not in the protocol	
35				
36				
37				
38	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	14
39			outcomes. Reference to where other details of the statistical	
40			analysis plan can be found, if not in the protocol	
41				
42				
43	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and adjusted	14
44	analyses		analyses)	
45				
46				
47	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	14
48	population and missing		adherence (eg, as randomised analysis), and any statistical	
49	data		methods to handle missing data (eg, multiple imputation)	
50				
51				
52	Methods: Monitoring			
53				
54				
55	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary of	20
56	formal committee		its role and reporting structure; statement of whether it is	
57			independent from the sponsor and competing interests; and	
58				
59				
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1		reference to where further details about its charter can be found,	
2		if not in the protocol. Alternatively, an explanation of why a	
3		DMC is not needed	
4			
5	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	20
6	interim analysis	including who will have access to these interim results and make	
7		the final decision to terminate the trial	
8			
9			
10			
11	Harms	#22 Plans for collecting, assessing, reporting, and managing solicited	12
12		and spontaneously reported adverse events and other unintended	
13		effects of trial interventions or trial conduct	
14			
15			
16	Auditing	#23 Frequency and procedures for auditing trial conduct, if any, and	NA
17		whether the process will be independent from investigators and	
18		the sponsor	
19			
20			
21	Ethics and		
22	dissemination		
23			
24			
25	Research ethics	#24 Plans for seeking research ethics committee / institutional	5
26	approval	review board (REC / IRB) approval	
27			
28			
29	Protocol amendments	#25 Plans for communicating important protocol modifications (eg,	6
30		changes to eligibility criteria, outcomes, analyses) to relevant	
31		parties (eg, investigators, REC / IRBs, trial participants, trial	
32		registries, journals, regulators)	
33			
34			
35			
36	Consent or assent	#26a Who will obtain informed consent or assent from potential trial	7
37		participants or authorised surrogates, and how (see Item 32)	
38			
39			
40	Consent or assent:	#26b Additional consent provisions for collection and use of	NA
41	ancillary studies	participant data and biological specimens in ancillary studies, if	
42		applicable	
43			
44			
45	Confidentiality	#27 How personal information about potential and enrolled	10;12
46		participants will be collected, shared, and maintained in order to	
47		protect confidentiality before, during, and after the trial	
48			
49			
50	Declaration of interests	#28 Financial and other competing interests for principal	19
51		investigators for the overall trial and each study site	
52			
53			
54	Data access	#29 Statement of who will have access to the final trial dataset, and	19
55		disclosure of contractual agreements that limit such access for	
56		investigators	
57			
58			
59			
60			

1	Ancillary and post trial	#30	Provisions, if any, for ancillary and post-trial care, and for	16
2	care		compensation to those who suffer harm from trial participation	
3				
4				
5	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial results	20
6	trial results		to participants, healthcare professionals, the public, and other	
7			relevant groups (eg, via publication, reporting in results	
8			databases, or other data sharing arrangements), including any	
9			publication restrictions	
10				
11				
12				
13	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	19;20
14	authorship		professional writers	
15				
16				
17	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	20
18	reproducible research		participant-level dataset, and statistical code	
19				
20				
21	Appendices			
22				
23	Informed consent	#32	Model consent form and other related documentation given to	25;26;27;28
24	materials		participants and authorised surrogates	
25				
26				
27	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	NA
28			biological specimens for genetic or molecular analysis in the	
29			current trial and for future use in ancillary studies, if applicable	
30				
31				

Notes:

- 34
- 35 • 18a: 10;11;12;13
- 36
- 37 • 18b: 10;11;12;13
- 38
- 39 • 32: 25;26;27;28 The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution
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- 41 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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BMJ Open

Clinical Outcomes and Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

Journal:	<i>BMJ Open</i>
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1
2
3 1 **1. Title:** Clinical Outcomes and Cost-Utility of Rotator Cuff Repair Surgery by Open and
4
5
6 2 Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial

7
8 3 **1a. Short title:** Cost-utility of open and arthroscopic rotator cuff repair

9
10
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23 **2. Abstract**

24 Introduction: Rotator cuff injuries account for up to 70% of pain in the shoulder. However,
25 there is still no consensus on the best surgical treatment of patients with rotator cuff injuries,
26 regarding the cost-effectiveness and cost-utility analysis between the open and arthroscopic
27 methods of rotator cuff repair. The objective of this trial is to compare the efficacy, cost-
28 effectiveness and cost-utility of open and arthroscopic procedure for rotator cuff repair.

29 Methods and Analysis: The trial is a two-group, parallel design, randomized controlled
30 trial. A total of 100 patients with symptomatic rotator cuff lesion will be allocated in either open
31 or arthroscopic technique in a 1:1 ratio, considering smoking (yes or no), lesion size (less than 3
32 cm or more than 3 cm) and diabetes (present or absent) as stratification factors. All patients will
33 be included in the same rehabilitation program after the intervention. The primary outcomes
34 measure will be the Constant-Murley score and EuroQol 5-D-3L at 48 weeks post-surgery.
35 Secondary outcomes include cost-effectiveness, cost-utility, pain, complications and clinical
36 analysis, using the simple shoulder test (SST), Visual Analogue Pain Scale (VAS), integrity of the
37 repair evaluated through magnetic resonance imaging, complications and failures of the proposed
38 methods. For the cost-effectiveness analyses, we will use the VAS and the Constant-Murley Score
39 as measures of effectiveness; for the cost-utility analyses, we will use the EuroQol- 5D-3L as a
40 measure of utility in terms of incremental cost per quality-adjusted life-years (QALY).

1
2
3 41 Ethics and Dissemination: The study has been approved by the local Research Ethics
4
5 42 Committee from both institutions: Hospital Israelita Albert Einstein and Hospital Alvorada
6
7 43 Moema/ Hospital Pró-Cardíaco. The results will be published in a peer-review open access journal.
8
9

10
11 44 Trial Registration Number: NCT04146987
12

13
14 45 Keywords: rotator cuff; surgery; arthroscopy; open repair; cost-effectiveness; QALY
15

16 17 46 **Strengths and limitations of this study**

- 18
19
20 47 • This study is a prospective, randomized trial, that is the best design to address the study
21
22 48 question. Its methodological analyses are the best option to determine cost-utility and will
23
24 49 provide a strong evidence.
25
26 50 • It will provide surgeons and healthcare providers with important information about the
27
28 51 surgical technique and the cost-effectiveness and cost-utility of these techniques
29
30 52 • This study will provide important information about rotator cuff healing and retear rates,
31
32 53 what is still unclear in the literature
33
34 54 • The lack of blinding of the patient and surgeons is a limitation to the study design
35
36
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39

40 55 **3. Introduction**

41 42 43 44 56 **3a. Background and Rationale**

45
46
47 57 Musculoskeletal injuries are a major cost to the healthcare system. North American data
48
49 58 estimate that approximately 4.5 million patients annually seek medical attention due to shoulder
50
51 59 pain; of these, two million have some symptoms related to the rotator cuff. About 250,000 rotator
52
53 60 cuff repair surgeries are performed annually in the United States of America (US), and with the
54
55
56

1
2
3 61 continued increase in life expectancy and aging, there is a tendency to increase this
4
5 62 number[1][2][3]. An evaluation of the primary health care system in Cambridge, United Kingdom,
6
7 63 showed that the average frequency of shoulder pain was 9.5 per 1,000 individuals [4]. Of those,
8
9 64 86% had rotator cuff tendinopathy.

10
11
12
13 65 The rotator cuff is a group of four muscles and their tendons that act to stabilize the
14
15 66 shoulder and allow for its extensive range of motion. Four muscles and their attached tendons
16
17 67 make up the rotator cuff: the subscapularis, supraspinatus, infraspinatus, and teres minor. The long
18
19 68 portion of the biceps tendon also contributes to cuff function, which is to stabilize the humeral
20
21 69 head in the glenoid cavity, preventing superior migration of the humeral head [5].
22
23
24

25 70 The possible lesions range from tendon degeneration (tendinosis/tendinopathy), through
26
27 71 partial tear (articular, interstitial or bursal), to complete tear. Its etiology is multifactorial and the
28
29 72 main factors associated with tears are tendon degeneration related to aging, trauma, tendon
30
31 73 insertion hypovascularity and genetic factors[6][7][8]. Since most lesions are caused by wear and
32
33 74 degeneration related to aging, people over 40 years are at greater risk[3]. Diagnosis is made by
34
35 75 associating history and physical examination along with imaging methods, and magnetic
36
37 76 resonance imaging (MRI) is considered the method of choice [9]–[17].
38
39
40
41

42 77 Treatment of rotator cuff lesion depends on the type of tear, the patient's functional
43
44 78 capacity, age, and the presence of symptoms. In general, tendon degeneration and partial tears are
45
46 79 treated non-surgically, with physiotherapy, injections and analgesic medications. Complete and
47
48 80 incomplete tears that did not respond well to conservative treatment, however, might be treated
49
50 81 surgically [12], [18]–[20][3][21][22].
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1
2
3 82 Among the surgical options, the open method is still considered the gold standard, with
4
5 83 good or excellent results in over 90% of cases [23]–[25]. Due to arthroscopy and the evolution of
6
7 84 arthroscopic instruments and implants in the last two decades, the arthroscopic repair technique
8
9
10 85 has gained space and is widely used. Some studies [23]–[26] did not show superiority of one
11
12 86 technique over another in terms of clinical outcomes. On the other hand, since the cost of
13
14 87 arthroscopic surgery is supposedly higher, due to the required equipment, it is important to
15
16 88 establish which option has the best cost-utility ratio. Other published studies suggested that the
17
18 89 open method is superior than the arthroscopic method in relation to cost-utility [27]–[29]. To date,
19
20 90 no study in our country has assessed the comparison of the cost-utility of the two techniques;
21
22 91 considering that the open technique is being left behind, is important to determine if it remains a
23
24 92 viable, reliable and cost-effective option for the treatment of rotator cuff tears.
25
26
27
28

29 93 **3b. Objectives**

30
31
32 94 Despite the high incidence of rotator cuff tears, there is no consensus about the best method
33
34 95 of repair, neither which method has the best cost-effectiveness and cost-utility ratio. Therefore, the
35
36 96 present study aims to compare the open and arthroscopic methods for rotator cuff repair and
37
38 97 determine which presents the best cost-effectiveness ratio.
39
40
41

42 98 **4. Trial Design**

43
44
45 99 The trial will be a prospective randomized controlled clinical trial.
46
47

48 100 **5. Methods**

49
50
51 101 This randomized controlled trial will follow the Consolidated Standards of Reporting Trials
52
53 102 (CONSORT) Statement [30]; also the protocol was developed following the SPIRIT
54
55
56
57
58
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1
2
3 103 guidelines[31]. It will be performed at Hospital Alvorada Moema (Shoulder and Elbow Surgery
4
5 104 Center of Excellence), São Paulo, Brazil. The cost analysis will be performed by Hospital Israelita
6
7
8 105 Albert Einstein team, São Paulo, Brazil. The project was approved by both hospitals research ethics
9
10 106 committee and registered in clinicaltrials.gov.

14 107 **5a. Sample size**

16
17 108 The sample size estimate was obtained to detect differences between the open and
18
19 109 arthroscopic repair groups in relation to the primary outcome of the study, Constant-Murley Score
20
21 110 (CM) instrument after the intervention. Kukkone's et al. 2013 study [32] estimated the clinically
22
23 111 important minimal difference in CM score in 10.4 points in patients with rotator cuff rupture after
24
25 112 3 months of surgical treatment by the arthroscopic method. The estimated sample size of 45
26
27 113 patients per group, total of 90 patients, would reach 90% power to detect a 10.4 difference between
28
29 114 the groups in the CM instrument post-operative score with a standard deviation of up to 15 points
30
31 115 with a significance level of 5% using a t-Student test. Predicting a loss of around 10% at 12 months
32
33 116 of follow-up we aim to recruit 50 patients per group (PASS software [33]).

39 117 **5b. Inclusion criteria**

41
42 118 All patients eighteen years of age or older, presenting with complete rotator cuff tear or a
43
44 119 partial rotator cuff tear of at least 50% of tendon thickness, with symptoms (pain and/or weakness),
45
46 120 where conservative therapy failed will be included. The tendon tear will be confirmed by a
47
48 121 Magnetic Resonance Imaging (MRI).

122 **5c. Exclusion criteria**

123 Patients with previous shoulder surgery, previous fractures in the affected shoulder, those
124 with passive range of motion limitation (joint stiffness with an elevation of 90 degrees or less),
125 radiographic signs of glenohumeral osteoarthritis or neurologic injury will be excluded. Patients
126 will also be excluded if they do not wish to participate or are unable to understand or sign the
127 informed consent form (due to conditions such as cognitive impairment, or mental illness) or if
128 there are any medical conditions that contraindicate any of the surgical methods.

129 **5d. Randomization and allocation**

130 After eligibility assessment, all patients will be informed about the nature and purpose of
131 the study and will only be included after agreeing with the study and signing the informed consent
132 form, that will be obtained by the surgeon that evaluated the patient and indicated the surgery.
133 Patients will be consecutively allocated to one of two proposed treatment methods: open rotator
134 cuff repair or arthroscopic rotator cuff repair. The software R was used to generate a randomization
135 list, considering 100 patients to be included in the study and the same probability of allocation for
136 both methods of surgery (open and arthroscopic repair). A stratified randomization will be
137 performed using the following variables (strata): smoking (yes or no), the size of the lesion (≤ 3
138 cm or > 3 cm) and diabetes (present or absent). Randomization will be performed by the REDCap
139 platform (Research Electronic Data Capture – Vanderbilt University)[34][35] after the patient is
140 anesthetized and prepared for the surgery. A person not associated with the study will open the
141 software and acquire one of the two techniques possible and tell the surgeon who will perform the
142 surgery.

143 **5e. Recruitment**

1
2
3 144 All patients that already would be treated by the shoulder surgeons at Hospital Alvorada
4
5 145 Moema (Shoulder and Elbow Surgery Center of Excellence), São Paulo, Brazil, will be enrolled
6
7
8 146 in this trial.
9

11 147 **5f. Blinding**

12
13
14 148 Due to the type of interventions, neither participants nor treatment providers can be blinded
15
16
17 149 to treatment allocation. The outcome assessment of the primary and secondary outcomes
18
19 150 (Constant-Murley; EuroQol; VAS and SST), patient-reported outcomes, will not be blind. One of
20
21 151 the authors (RP) will assess all other clinical outcomes. The statisticians conducting the analyses
22
23
24 152 will be blinded to the treatment status until the analyses are completed.
25

26 153 **5g. Ethics and Dissemination**

27
28
29 154 The study has been approved by the local Research Ethics Committee from both
30
31
32 155 institutions: Hospital Israelita Albert Einstein (CAAE 19182619.3.1001.0071) and Hospital
33
34 156 Alvorada Moema/ Hospital Pró-Cardíaco (CAAE 19182619.3.2002.5533). Digital, informed
35
36 157 consent (supplementary material) to participate will be obtained from all participants through
37
38
39 158 software REDCAP[35][34].
40

41
42 159 This study was developed and will follow the International Conference Guideline for Good
43
44 160 Clinical Practice (ICH GP) to assure that the data and results are credible and that the rights,
45
46 161 integrity and confidentiality of the trial subjects are protected and respected[36][37].
47
48

49 162 All authors agreed to publish the results of the present study in a peer-reviewed open access
50
51 163 journal, despite the results and conclusions found. All data will be available upon request.
52
53

54 164 **5h. Patient and Public Involvement**

1
2
3 165 The patients nor the public were involved on the design and development of this study.
4
5
6 166 Their participation will first occur with the contact between the surgeon and patient, when they
7
8 167 will be informed about the study and will decide to participate or not. At that time, they will be
9
10 168 informed about the purpose and importance of it. During the entire follow-up the patients will be
11
12 169 able to enquiry the researchers and surgeons about the project and to make suggestions and
13
14
15 170 complaints about it.

16
17
18 171 All the outcomes measures will be self-reported. The patients will be assisted by one
19
20 172 member of the research team, if they have any questions or doubts.

21
22
23 173 Since the authors agreed to publish the results of this research, patients will not be involved
24
25 174 on the dissemination. However, they will be encouraged to disseminate the knowledge among the
26
27 175 community.

30 31 176 **6. Intervention methods**

32
33
34 177 Five surgeons with at least four years of surgical technique experience will participate in
35
36 178 this study (EFC, MTCA, RP, BAM, VR). Also, the residents of shoulder and elbow surgery, as
37
38
39 179 well as the residents of Orthopedics and Traumatology from Hospital Alvorada Moema and
40
41 180 residents in shoulder and elbow surgery at Albert Einstein Hospital may participate in surgeries.

42
43
44 181 Open surgery: patients will be positioned in a beach chair position with the affected limb
45
46 182 pending off the table, allowing manipulation and full range of motion. After standard patient
47
48
49 183 preparation, an anterolateral incision will be made in the shoulder; the deltoid muscle belly will be
50
51 184 gently divided along its fibers until exposure of the subdeltoid / subacromial bursa, which will be
52
53 185 partially excised for exposure of the subacromial space and rotator cuff tendons. After mobilization

1
2
3 186 and release of the ruptured tendons and debridement of the rotator cuff footprint, the tendon repair
4
5 187 to the bone will be performed using 5.5mm metal anchors (“Super Revo”-CONMED, USA),
6
7
8 188 according to the preference and technique chosen by the surgeon. In all cases, the release of the
9
10 189 coracoacromial ligament and acromioplasty will be performed.

13 190 Arthroscopic Technique: the patients will be positioned in lateral decubitus position, with
14
15 191 the limb to be operated attached to a skin traction device, which through a traction post and 7
16
17 192 kilograms (kg), will maintain the shoulder in the following position: abduction of 30 to 60 degrees
18
19 193 and flexion of 20 to 30 degrees. After standard patient preparation, a posterolateral incision will
20
21 194 be made in the shoulder for optic introduction, with a 50mmHg pressure pump and a 0.90 flow,
22
23 195 and inspection of the glenohumeral joint. After establishment of all required arthroscopic portals,
24
25 196 joint inspection will be performed and any, if present, associated pathologies will be addressed.
26
27 197 With the use of shaver blades, partial bursectomy will be performed and any adherence to the
28
29 198 tendon stumps will be released, as well as debridement of the rotator cuff footprint. The tendon
30
31 199 will then be reinserted to the bone using metallic 5.5mm anchors (“Super Revo”-CONMED,
32
33 200 USA), according to the preference of each surgeon. The technique used, as well as the suture
34
35 201 configuration and type of knot used, will be defined by the surgeon, according to his preference.
36
37 202 After tendon repair, the coracoacromial ligament will be released, as well as acromioplasty will be
38
39 203 performed.
40
41
42
43
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45
46

47 204 **7. Postoperative rehabilitation**

49
50 205 All patients will undergo the same postoperative rehabilitation protocol: use of Velpeau
51
52 206 sling for 6 weeks; pendulum exercises starting on second week; active movement and recovery of
53
54 207 the range of motion from the sixth week and strengthening from the twelfth week.

1
2
3 208 The patients will be oriented to perform home exercises and to be assisted by a
4
5 209 physiotherapist twice a week from the sixth week of surgery and on. Approximately thirty sessions
6
7
8 210 of physical therapy will be expected.
9

10 211 **8. Outcomes assessment**

11
12
13 212 Study data will be collected and managed using REDCap (Research Electronic Data
14
15
16 213 Capture- “Vanderbilt University, Nashville, Tennessee, USA”) hosted at Hospital Israelita Albert
17
18 214 Einstein [34][35]. REDCap is a secure, web-based software platform designed to support data
19
20
21 215 capture for research studies, providing: 1) an intuitive interface for validated data capture; 2) audit
22
23 216 trails for tracking data manipulation and export procedures; 3) automated export procedures for
24
25 217 seamless data downloads to common statistical packages; and 4) procedures for data integration
26
27 218 and interoperability with external sources.
28
29

30 219 All study participants will be evaluated preoperatively, at the hospital discharge and 1, 2,
31
32 220 6, 24 and 48 weeks after the intervention. The Constant-Murley score, Visual Analogue Scale,
33
34 221 EuroQol-5D-3L and the Simple Shoulder Test questionnaires will be filled out by the patient and
35
36
37 222 assessed by evaluators to the assigned intervention. The endpoint of cost-utility analysis will be
38
39 223 48 weeks; clinical outcomes will also be assessed at 6 and 24 weeks.
40
41
42

43 224 To prevent loss of follow-up all the patients will be monitored by REDCap software and
44
45 225 alerts will be sent to each patient near time points defined by the investigators. One week before
46
47 226 every medical consultation and at the twelfth week, during the rehabilitation process. If the patient
48
49 227 fails to fill any questionnaire or does not attend the medical consultations, he will be contacted by
50
51 228 phone and e-mail. If a patient becomes not reachable at any time of the follow-up, we will consider
52
53 229 a lost follow-up scenario, where, in accordance with the intention to treat principle, appropriate
54
55
56

1
2
3 230 statistical methods for data analysis, that consider unbalanced data and loss of follow-up, such as
4
5 231 Generalized Estimating Equation Model (GEE), will consider all patients observations, even if
6
7
8 232 they fail in some moment. Thereby, these patients will not be excluded, and all data will be
9
10 233 considered.

13 234 **9. Primary outcome**

16 235 The Brazilian Portuguese Version of the Constant-Murley Score (CM) [38] will be
17
18 236 measured preoperatively at 6, 24 and 48 weeks after the intervention. Research assistants (not
19
20 237 blinded to the study aim) will ask the patients to fill in the validated CM form in Portuguese and
21
22 238 measure the range of motion with an analogic goniometer. The CM scale covers different domains
23
24 239 of shoulder function (pain, activities of daily living, range of motion and power), punctuating each
25
26 240 of them; it ranges from 0 to 100, with higher scores indicating better function[38]. The constant-
27
28 241 Murley score is one of the most commonly used scores on shoulder scoring system and is considered the
29
30 242 gold-standard in Europe[39][40]. It is reliable for detection of shoulder improvement after surgical
31
32 243 procedures and its strong correlation with shoulder specific diseases, especially rotator cuff, and reliability
33
34 244 makes it a good score system for a clinical research.

39 245 EuroQol-5D-3L (European Quality of Life), a generic score developed to describe health-
40
41 246 related quality of life [30] will also be assessed preoperatively, at 6, 24 and 48 weeks
42
43 247 postoperatively. This score includes five health domains: mobility, self-care, usual activities,
44
45 248 pain/discomfort, and anxiety/depression; each domain has 3 levels: no problem; some problems
46
47 249 and extreme problems. In addition, the EuroQol-5D-3L has a visual analog scale where the
48
49 250 participant assigns a value between 0 and 100 to his or her own health condition, where 100 means
50
51 251 “the best imaginable health status” or “the best health state you can imagine” and 0 means “the
52
53 252 worst imaginable health state” or “the worst health state you can imagine”. This is used to obtain
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3 253 a respondent's stated preference values, not to record their own health state. [41]. At the end of
4
5 254 its application, EuroQol-5D-3L will provide a unique numerical value that can be used for
6
7
8 255 longitudinal comparison between different time periods.
9

10 256 **9b. Secondary outcomes**

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14 257 Clinical outcomes will also be assessed by the Simple Shoulder Test (SST), validated for
15
16 258 Portuguese [42], preoperatively and at 6, 24 and 48 weeks after the procedure. SST is a simple,
17
18 259 quick and widely used questionnaire for shoulder function measurement; it consists of 12
19
20
21 260 dichotomous questions answered by the patient himself. Each positive answer (yes) is given a
22
23 261 score; at the end of the questionnaire the percentage of positive answers (score) is made, and the
24
25 262 higher the percentage, the better the shoulder function. Other outcomes measured will be VAS
26
27 263 (visual analogue pain scale) at hospital discharge, 1, 2, 6, 24 and 48 weeks after the intervention.
28
29
30 264 This scale allows pain intensity to be measured with maximum interobserver reproducibility; it
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32 265 consists of a 10 cm straight line with the ends determining the limits of pain sensation (no pain;
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34 266 worst pain ever experienced); the distance between zero (no pain) and the patient's demarcation
35
36
37 267 defines the intensity of pain[43].
38

39
40 268 Complications and failures of the proposed methods will also be assessed. Failures will be
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42 269 characterized as the need for additional surgical procedures and/or change of the initially proposed
43
44 270 procedure. Patients who, for any reason, demonstrate treatment failure or require additional
45
46
47 271 interventions will be followed up and their results included in the group in which they were initially
48
49 272 randomized, according to the intention to treat principle.
50

51
52 273 At the final follow-up (forty-eight weeks), the integrity and healing of repaired rotator cuff
53
54 274 will be assessed through Magnetic Resonance Imaging (MRI).
55
56

275 **9c. Cost-effectiveness**

276 Cost-effectiveness and cost-utility analyses will be assessed by the estimate of direct and
 277 indirect costs to the private healthcare system at 48 weeks. The perspective adopted in the study
 278 will be the social costs, the direct and indirect medical costs. The set timeframe will be 48 weeks
 279 and a sensitivity analysis will be performed with the costs data, considering 0% to 5% discount
 280 rate to define the optimal discount rate for the data, according to methodological Guidelines for
 281 Economic Evaluation of Health Technologies – Brazilian Ministry of Health[44], [45][46]. The
 282 costs included in direct medical costs will be: hospitalization, costs related to arthroscopic
 283 instruments (e.g. cannulas, shaver blades, suture passer, ablator) medical fees, medication; the
 284 indirect costs: costs of absence from work, which will be estimated by the patient-reported number
 285 of days away from work multiplied by the average wage rate of the current year. The costs will be
 286 converted from Brazilian Reais to US dollars and brought to the cost schedule of the current year,
 287 in order to avoid that the effect of inflation on the medical inputs influences the analysis. For the
 288 cost-effectiveness analysis, the VAS and the CM will be used as measures of effectiveness. For
 289 the cost-utility analysis, the EuroQOL-5D-3L will be used as a measure of utility. The timetable
 290 of outcomes assessment is described on Table 1.

291 **Table1.** Timetable of assessment

STUDY PERIOD								
	Enrolment	Allocation	Post-Allocation				Close -Out	
TIMEPOINT	0	0	Surger y	1 w	2 w	6 w	24 w	48w

1.

ENROLMENT:								
Eligibility Screen	X							
Informed Consent	X							
CM; EQ-5D, SST;	X							
VAS	X							
Allocation		X						
INTERVENTIONS								
Open Repair			X					
Arthroscopic Repair			X					
ASSESSMENTS:								
CM; EQ-5D, SST;						X	X	X
VAS			X	X	X	X	X	X
MRI	X							X
Complications			X	X	X	X	X	X
Economics			X	X	X	X	X	X

292

293 10. Data analysis

294 The descriptive analyses of variables will be based on the absolute frequencies and
 295 percentages for categorical variables and summary measures as means and standard deviations or
 296 medians and quartiles, as well as minimum and maximum values for numerical variables [47].

1.

1
2
3 297 Clinical scores will be represented by individual profile graphs separately by the surgical technique
4
5 298 group.

6
7
8 299 The groups will be compared according to the presence of categorical clinical outcomes
9
10 300 (failures, complications and healing integrity) by Chi-square or Fisher's exact tests, depending on
11
12 301 the distribution observed after data collection.

13
14
15 302 For inferential analysis of continuous variables clinical outcomes, mixed models will be
16
17 303 used and, if the normal distribution is not adequate, generalized mixed models will be used [48].
18
19 304 The models will have time effects (preoperative, 6, 24 and 48 weeks after intervention), surgical
20
21 305 technique group (open repair or arthroscopic repair) and the interaction effect between time and
22
23 306 group. The size of the lesion (smaller than three cm or larger than three cm) will also be included
24
25 307 in the models as a control variable, seeking to avoid possible biases.

26
27
28 308 The analyzes will be performed with the aid of the SPSS program (SPSS Inc., Chicago,
29
30 309 Illinois, USA) [49], considering a significance level of 5%.

31 310 **11. Safety**

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38 311 There will be no benefit to the participant, beyond what is expected for the correction of
39
40 312 the rotator cuff tear, expecting an improvement of pain and function of the affected shoulder. The
41
42 313 risks of the present study are those inherent in any surgical treatment and anesthetic procedure,
43
44 314 such as surgical wound infection, scar formation, pain, decrease in shoulder range of motion,
45
46 315 rotator cuff tear, neurovascular injury. If any complications occur, all patients will be treated by
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48 316 the same surgical team until the complication is healed.

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52 317 Both surgical techniques have the same goal, that is, to repair the ruptured tendon to the
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54 318 bone. The open technique requires a larger incision, as well as greater surgical dissection and

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3 319 manipulation of the deltoid muscle, which may cause greater postoperative pain and weakness of
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5 320 this muscle, in addition to causing a slightly larger scar. However, it provides great visualization
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8 321 and manipulation and mobilization capability of the ruptured tendon, which provides a safer and
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10 322 tension-free repair.

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12
13 323 The arthroscopic technique is performed with some point-shaped cuts in the shoulder,
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15 324 usually three or four; due to smaller incisions, it requires less muscle manipulation, which
16
17 325 theoretically would cause less postoperative pain and less muscle weakness of the deltoid muscle,
18
19
20 326 it also has minor scars. However, this technique requires more surgeon's experience and the
21
22 327 mobilization of the ruptured tendon(s) is limited. Using a large amount of saline may cause edema
23
24 328 in the operated shoulder, which is usually resolved after the first 12 hours of surgery.

25
26
27 329 Finally, there is a minimal risk of loss of data confidentiality; all data will be managed,
28
29
30 330 stored and protected by REDCAP software[34], [35]. Only the main investigator will have access
31
32 331 to all data during the entire trial period. Any adverse event will be reported to the researchers
33
34 332 involved and communicated to the main investigator according to the Institutional Review Boards
35
36
37 333 description.

38 39 40 334 **12. Discussion**

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42
43 335 There is no consensus about the best cost-effectiveness of surgical treatment of patients
44
45 336 with degenerative rotator cuff injuries. Several studies [27], [28], [50], [51] suggest that the open
46
47 337 repair method is more cost-effective than the arthroscopic method, resulting in the same clinical
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49
50 338 outcome with lower cost. Adla, Deepthi N. et. al [27] in a prospective nonrandomized study,
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52 339 showed that both techniques lead to the same clinical outcomes. The costs of arthroscopic surgery
53
54 340 were higher than the open surgery, mainly due to the costs of the suture anchors, which was used

1
2
3 341 only in the arthroscopic group, is important to notice that in most of the open surgeries, the repair
4
5 342 was performed through transosseous sutures. Köse, Kamil Çağrı et. al [28], in a retrospective
6
7 343 study, also demonstrated similar clinical outcomes, although the costs of arthroscopic procedure
8
9 344 being much higher. Importantly, the open repair technique was performed using transosseous
10
11 345 sutures and the arthroscopic method using suture anchors and also, the open repair group required
12
13 346 longer length hospital stay. Hui, Yik Jing et. al [50] in a retrospective cohort study, described a
14
15 347 significantly higher cost for the arthroscopic procedure, compared to the open repair, evaluating
16
17 348 only the in-hospital costs, but with the same clinical outcomes. However, it is important to
18
19 349 emphasize that the open repair was performed using transosseous sutures, without suture anchors
20
21 350 and that the arthroscopic group needed a longer surgery time. Churchill, R.S. et. al [51] using the
22
23 351 New York Ambulatory Database System, with a total of 5,224 cuff repair surgeries, of which
24
25 352 1,334 open repair and 3,890 arthroscopic repair, showed that the mini-open rotator cuff repair costs
26
27 353 significantly less than the arthroscopic repair and requires significantly less surgical time.
28
29 354 However, no clinical outcomes have been analyzed in this study, making it impossible to determine
30
31 355 the cost-effectiveness ratio. An important study by Carr, A.J. et. al [52] carried out as a prospective
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33 356 multicenter randomized clinical trial, concluded that there is no difference in the effectiveness and
34
35 357 cost-effectiveness between the open repair surgery and arthroscopic surgery after 24 months of
36
37 358 follow-up, even with the higher initial costs in the arthroscopy surgery. An economic evaluation
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39 359 of the data from this study was carried out, showing that the Incremental Cost Effectiveness (ICER)
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41 360 was uncertain and the arthroscopic repair surgery was slightly more costly and less effective than
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43 361 open repair surgery.
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52 362 Thus, despite the high incidence of rotator cuff tear, there is insufficient evidence to
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54 363 determine the best method for treating these injuries. So, the present study proposes to answer the

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2
3 364 clinical question of which method, open or arthroscopic, presents the best cost-utility in the
4
5 365 surgical treatment of rotator cuff tear. Providing conclusive, good quality evidence for and
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7
8 366 contributing to the evidence base of methods used to treat rotator cuff injuries.
9

10 367 **13. Trial status**

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14 368 Protocol Trial version: 5 Date: 12/11/2020

15
16
17 369 Recruitment Start Date: August/2020

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19
20 370 Recruitment Estimated End Date: December/2021

21
22
23 371 Recruiting

24 25 372 **14. Additional files (Supplementary Material)**

26
27
28 373 **Table 1.** Timetable of assessment

29
30
31 374 Informed Consent

32
33
34 375 Ethical Committee Review

35
36
37 376 SPIRIT Checklist

38 39 40 41 377 **15. Abbreviations**

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43
44 378 CONSORT: Consolidated standards of reporting trials; VAS: Visual analogue scale; MRI:

45
46 379 magnetic resonance imaging; QALY: quality-adjusted life years; CM: Constant-Murley Score;

47
48
49 380 SST: Simple Shoulder Test

50 51 52 381 **16. Declarations**

382 **16.1 Ethics Approval and Consent to Participate**

383 The study has been approved by the local Research Ethics Committee from both
384 institutions: Hospital Israelita Albert Einstein (CAAE 19182619.3.1001.0071) and Hospital
385 Alvorada Moema/ Hospital Pró-Cardíaco (CAAE 19182619.3.2002.5533). Digital, informed
386 consent to participate will be obtained from all participants through software REDCAP[35][34].

387 All and any modifications in this study will be promptly reported to all Research Ethics
388 Committee, all institutions, all investigators and all participants.

389 **16.2 Consent for Publication**

390 Not Applicable

391 **16.3 Availability of Data and Materials**

392 The datasets used and/or analyzed during the current study will be available from the
393 corresponding author upon request.

394 **16.4 Competing interests**

395 The authors declare that they have no competing interests.

396 **16.5 Funding**

397 This study is supported by Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP
398 2019/02159-3).

399 **16.6 Registry**

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2
3 400 The project is registered in the clinicaltrials.gov database (NCT04146987
4
5 401 <https://clinicaltrials.gov/ct2/show/NCT04146987?term=NCT04146987&draw=2&rank=1>).
6
7
8

9 402 **16.7 Contributorship Statement**

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11
12 403 All listed authors had a substantial contribution to the conceptions and development of this study,
13
14 404 revised, approved the final version and are accountable for all aspects of the study. We ensure that
15
16 405 all questions related to the accuracy or integrity of any part of the project are appropriately
17
18 406 investigated and resolved. Contributions were as follows:
19
20
21
22

23 407 ML is the Chief Investigator; he conceived the study, led the proposal and protocol
24
25
26 408 development.
27
28
29

30 409 RP is the lead trial methodologist and helped in the study conceiving and development
31
32
33

34 410 EA contributed to study design and to development of the proposal.
35
36
37

38 411 IO contributes to study design related to QALY
39
40
41

42 412 IQC is responsible for cost-analysis
43
44

45 413 FM helped in the English translation and registration/publication of the trial
46
47
48

49 414 PF helped in the English translation and registration/publication of the trial
50
51
52

53 415 EFC helped in the study conceiving and development
54
55

56 416 BAM helped in the study conceiving and development
57
58
59

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3 417 **16.8 Acknowledgements**
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5
6 418 Not applicable
7

8
9 419 **17. Dissemination policy**
10

11
12 420 All the authors are committed and agree to publish the full results of the research, despite the final
13
14 421 results.
15

16
17 422 **18. Data Monitoring Committee (DMC)**
18

19
20 423 Since this trial have a short duration and both surgical techniques have known minimal risks, there
21
22 424 is no need for such committee.
23
24

25
26 425 **19. References**
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TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Título do projeto: Custo-Efetividade da Cirurgia de Reparo do Manguito Rotador Pelas Técnicas Aberta e Artroscópica. Ensaio Clínico Randomizado.

Prezado,

Você foi convidado a participar da pesquisa intitulada “Custo-Efetividade da Cirurgia de Reparo do Manguito Rotador Pelas Técnicas Aberta e Artroscópica. Ensaio Clínico Randomizado”. Essas informações serão fornecidas por meio de sua participação voluntária neste estudo, com o objetivo de avaliar o custo-efetividade (benefícios e malefícios e os custos dos procedimentos) das intervenções: reparo aberto do manguito rotador e reparo artroscópico do manguito rotador.

A ruptura do manguito rotador, ou seja, o rompimento dos tendões do ombro é a principal de causa de dor no ombro na população adulta, causando, além da dor, diminuição da força no ombro acometido e diminuição na qualidade de vida do paciente, devido a dor constante e piora na qualidade do sono, causado pela dor. Existem duas técnicas cirúrgicas para correção desta doença: a técnica aberta, realizada por uma incisão (corte) no ombro e visualização direta do tendão rompido; e a técnica artroscópica, realizada através de pequenos corte no ombro, por onde são introduzidos câmera de vídeo, para visualização do tendão rompido através de monitor, e instrumentais para realização da cirurgia. A motivação da realização deste estudo se deve ao fato de encontrarmos na literatura atual dúvidas sobre qual método de reparo do manguito rotador apresenta a melhora relação custo-efetividade. Acreditamos que o reparo aberto do manguito rotador apresente os mesmos resultados funcionais e de qualidade de vida que o reparo artroscópico do manguito rotador, além de apresentar um custo menor.

Procedimentos a serem utilizados:

O número de participantes estimado é de 100 indivíduos, divididos em dois grupos, 50 para o grupo de reparo aberto do manguito rotador e 50 para o grupo de reparo artroscópico do manguito rotador. A seleção será feita de forma randomizada, isto é, não saberemos onde cada indivíduo será incluído.

Os dois grupos de pacientes receberão os mesmos cuidados e os mesmos seguimentos. As avaliações serão realizadas por meio de exames clínicos e funcionais (realizados por um médico) no pré-operatório, 6, 24 e 48 semanas após o procedimento cirúrgico, exame de ressonância magnética no pré-operatório e 48 semanas após o procedimento. O programa de reabilitação após as intervenções de tratamento será idêntico em cada um dos grupos comparados. Todos os pacientes utilizarão tipóia do tipo Velpau por seis semanas; depois de duas semanas da intervenção, você iniciará um programa de exercícios pendulares orientados pelo médico e após a sexta semana, a tipóia será retirada e você será orientado a realizar exercícios domésticos para ganho de arco de movimento (ADM), além de duas sessões semanais de fisioterapia para analgesia e recuperação da amplitude de movimento do ombro. Os exercícios de fortalecimento serão permitidos a partir da décima segunda semana, sob orientação de fisioterapeuta.

No término do estudo será verificado se houve melhora nas avaliações funcionais, de qualidade de vida e cicatrização do tendão reparado por meio de questionários de simples preenchimento e exame de ressonância magnética.

Você não terá benefício além do esperado para a operação de correção da lesão, esperando-se melhora da dor e função do ombro acometido. Os riscos do presente estudo são aqueles inerentes a qualquer tratamento cirúrgico e procedimento anestésico, como infecção da ferida operatória, formação de cicatriz, dor, limitação do arco de movimento do ombro, rerruptura do manguito rotador, lesão neurovascular. Ambas as técnicas cirúrgicas tem o mesmo objetivo, ou seja, reparar o tendão rompido ao osso. A técnica aberta necessita de uma incisão (corte) maior, além de maior dissecação cirúrgica e manipulação do músculo deltoide, o que pode provocar maior dor pós-operatória e fraqueza desse músculo, além de causar uma cicatriz pouco maior. Entretanto, ela provê uma grande visualização e capacidade de manipulação e mobilização do tendão rompido, o que proporciona um reparo mais

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Rubrica: 1) Paciente/Representante Legal/Testemunha Imparcial _____ 2) Responsável pelo consentimento _____



seguro e livre de tensão. Já a técnica artroscópica é realizada com alguns cortes puntiformes no ombro, geralmente três ou quatro; pelas incisões (cortes) menores, ela necessita de menos manipulação muscular, o que teoricamente causaria menos dor pós-operatória e menos fraqueza muscular do músculo deltoide; além disso, apresenta cicatrizes menores. No entanto, é uma técnica que demanda mais experiência do cirurgião e a mobilização do(s) tendão(ões) rompido(s) é limitada; a utilização de grande quantidade de soro fisiológico pode causar edema no ombro operado, o que geralmente é revertido após as primeiras 12 horas da cirurgia.

Trata-se de um estudo que testará a hipótese de que a cirurgia de reparo aberto do manguito rotador apresenta uma melhor relação custo-efetividade que a cirurgia de reparo artroscópico do manguito rotador. Somente no final do estudo poderemos determinar a presença de alguma diferença entre estes dois tipos de tratamento.

Em qualquer etapa do estudo, você terá acesso aos profissionais responsáveis pela pesquisa para esclarecimento de eventuais dúvidas. O coordenador do projeto é o Dr. Mário Lenza e o principal responsável pelo estudo é o Dr. Rafael Pierami, que podem ser encontrados: Dr. Mario Lenza – endereço Av. Albert Einstein, 627 – bloco A1 – 3º andar – Programa Locomotor, Morumbi, São Paulo – CEP 05652-900: Tel: (11) 2151.1444; e-mail: mario.lenza@einstein.br; e Dr. Rafael Pierami – endereço Avenida Ministro Gabriel Rezende de Passos, 550, 2º andar, Hospital Alvorada Moema – Centro de Excelência em Cirurgia de Ombro e Cotovelo, Moema, São Paulo – CEP 04521-022 – Tel: (11) 2186-9810 ou (11) 2186-9809; e-mail: rafael_pierami@hotmail.com.

Se você tiver qualquer dúvida ética em relação à pesquisa, entre em contato com o **Comitê de Ética em Pesquisa do Hospital Israelita Albert Einstein** - Av. Albert Einstein 627/701, fone 2151-3729, e-mail: cep@einstein.br ou o **Comitê de Pesquisa do Hospital Alvorada**- Av. Ministro Gabriel de Rezende Passos, 550, 2º andar, telefones 2186-9810 ou 2186-9809, e-mail: rafael_pierami@hotmail.com ou ainda o Comitê de Ética em Pesquisa em Seres Humanos do Hospital Pró-Cardíaco (CEP/HPC), Tel: (21) 3289-3802, Localizado na Rua Voluntários da Pátria, 435/8º andar, Botafogo, Rio de Janeiro, CEP: 22270-005 - Horário de atendimento: de segunda à sexta-feira, das 09:00h às 16:00h.

Reclamações, elogios e sugestões deverão ser encaminhados ao Sistema de Atendimento ao Cliente (SAC) por meio do telefone (11) 2151-0222 ou formulário identificado como fale conosco disponível na página da pesquisa clínica ou pessoalmente.

Você pode retirar o seu consentimento a qualquer momento e deixar de participar do estudo, sem qualquer prejuízo à continuidade de seu tratamento na Instituição.

Suas informações serão analisadas em conjunto com as informações de outros pacientes voluntários e não será divulgada a identificação de nenhum paciente. Você tem o direito de ser mantido atualizado sobre os resultados parciais das pesquisas e de quaisquer resultados que sejam do conhecimento dos pesquisadores. Não haverá nenhuma despesa pessoal para você em qualquer fase do estudo, incluindo exames e consultas, assim como também não há compensação financeira relacionada à sua participação.

Se você sofrer algum dano, previsto ou não neste termo de consentimento e relacionado com sua participação no estudo, a equipe que realizou o procedimento custeará as despesas médicas necessárias e decorrentes do estudo.

O pesquisador se compromete a utilizar os dados e materiais coletado durante o estudo somente para esta pesquisa, como descrito previamente.

Eu discuti com o Dr. Mário Lenza e/ou Dr. Rafael Pierami e/ou qualquer membro autorizado da equipe desta pesquisa, sobre a minha decisão em participar neste estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus eventuais desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia do acesso a tratamento hospitalar quando necessário. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.

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Rubrica: 1) Paciente/Representante Legal/Testemunha Imparcial _____ 2) Responsável pelo consentimento _____



Nome Completo do participante da pesquisa

Assinatura do participante da pesquisa Data: ___/___/___

Nome completo e legível do pesquisador responsável

Assinatura do pesquisador responsável Data: ___/___/___

Nome completo do representante legal

Assinatura do representante legal Data: ___/___/___

Relação do representante legal com o paciente

Nome completo da testemunha imparcial

****para casos de voluntários menores de 18 anos, analfabetos, semi-analfabetos ou portadores de deficiência auditiva ou visual.**

Assinatura da testemunha imparcial Data: ___/___/___

Número: _____

Iniciais: _____

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Rubrica: 1) Paciente/Representante Legal/Testemunha Imparcial _____ 2) Responsável pelo consentimento _____

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Title: Cost-Utility of Rotator Cuff Repair Surgery by Open and Arthroscopic Techniques: Study Protocol for a Randomized Clinical Trial.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	01
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	03
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	05
Protocol version	#3	Date and version identifier	17
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	18;19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	01
Roles and responsibilities: sponsor and funder	#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	06
Roles and responsibilities:	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee,	05

1	committees		data management team, and other individuals or groups	
2			overseeing the trial, if applicable (see Item 21a for data	
3			monitoring committee)	
4				
5	Introduction			
6				
7				
8	Background and	#6a	Description of research question and justification for	3;4;5
9	rationale		undertaking the trial, including summary of relevant studies	
10			(published and unpublished) examining benefits and harms for	
11			each intervention	
12				
13				
14	Background and	#6b	Explanation for choice of comparators	3;4;5
15	rationale: choice of			
16	comparators			
17				
18				
19	Objectives	#7	Specific objectives or hypotheses	5
20				
21				
22	Trial design	#8	Description of trial design including type of trial (eg, parallel	5
23			group, crossover, factorial, single group), allocation ratio, and	
24			framework (eg, superiority, equivalence, non-inferiority,	
25			exploratory)	
26				
27				
28				
29	Methods:			
30	Participants,			
31	interventions, and			
32	outcomes			
33				
34				
35				
36	Study setting	#9	Description of study settings (eg, community clinic, academic	5;6
37			hospital) and list of countries where data will be collected.	
38			Reference to where list of study sites can be obtained	
39				
40				
41	Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable,	6;7
42			eligibility criteria for study centres and individuals who will	
43			perform the interventions (eg, surgeons, psychotherapists)	
44				
45				
46	Interventions:	#11a	Interventions for each group with sufficient detail to allow	8;9
47	description		replication, including how and when they will be administered	
48				
49				
50	Interventions:	#11b	Criteria for discontinuing or modifying allocated interventions	12
51	modifications		for a given trial participant (eg, drug dose change in response to	
52			harms, participant request, or improving / worsening disease)	
53				
54				
55	Interventions:	#11c	Strategies to improve adherence to intervention protocols, and	10;11
56	adherence		any procedures for monitoring adherence (eg, drug tablet return;	
57			laboratory tests)	
58				
59				
60				

1	Interventions:	#11d	Relevant concomitant care and interventions that are permitted	NA
2	concomitant care		or prohibited during the trial	
3				
4				
5	Outcomes	#12	Primary, secondary, and other outcomes, including the specific	10;11;12
6			measurement variable (eg, systolic blood pressure), analysis	
7			metric (eg, change from baseline, final value, time to event),	
8			method of aggregation (eg, median, proportion), and time point	
9			for each outcome. Explanation of the clinical relevance of	
10			chosen efficacy and harm outcomes is strongly recommended	
11				
12				
13				
14	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-	13
15			ins and washouts), assessments, and visits for participants. A	
16			schematic diagram is highly recommended (see Figure)	
17				
18				
19				
20	Sample size	#14	Estimated number of participants needed to achieve study	6
21			objectives and how it was determined, including clinical and	
22			statistical assumptions supporting any sample size calculations	
23				
24				
25	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach	8
26			target sample size	
27				
28				
29	Methods: Assignment			
30	of interventions (for			
31	controlled trials)			
32				
33				
34	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, computer-	7;8
35	generation		generated random numbers), and list of any factors for	
36			stratification. To reduce predictability of a random sequence,	
37			details of any planned restriction (eg, blocking) should be	
38			provided in a separate document that is unavailable to those who	
39			enrol participants or assign interventions	
40				
41				
42				
43				
44	Allocation	#16b	Mechanism of implementing the allocation sequence (eg, central	7;8
45	concealment		telephone; sequentially numbered, opaque, sealed envelopes),	
46	mechanism		describing any steps to conceal the sequence until interventions	
47			are assigned	
48				
49				
50				
51	Allocation:	#16c	Who will generate the allocation sequence, who will enrol	7;8
52	implementation		participants, and who will assign participants to interventions	
53				
54				
55	Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial	8
56			participants, care providers, outcome assessors, data analysts),	
57			and how	
58				
59				
60				

1	Blinding (masking):	#17b	If blinded, circumstances under which unblinding is permissible,	8
2	emergency unblinding		and procedure for revealing a participant's allocated intervention	
3			during the trial	
4				
5				
6	Methods: Data			
7	collection,			
8	management, and			
9	analysis			
10				
11				
12				
13	Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and	10;11;12;13
14			other trial data, including any related processes to promote data	
15			quality (eg, duplicate measurements, training of assessors) and a	
16			description of study instruments (eg, questionnaires, laboratory	
17			tests) along with their reliability and validity, if known.	
18			Reference to where data collection forms can be found, if not in	
19			the protocol	
20				
21	Data collection plan:	#18b	Plans to promote participant retention and complete follow-up,	10;11;12;13
22	retention		including list of any outcome data to be collected for	
23			participants who discontinue or deviate from intervention	
24			protocols	
25				
26				
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30				
31	Data management	#19	Plans for data entry, coding, security, and storage, including any	10;11
32			related processes to promote data quality (eg, double data entry;	
33			range checks for data values). Reference to where details of data	
34			management procedures can be found, if not in the protocol	
35				
36				
37				
38	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary	14
39			outcomes. Reference to where other details of the statistical	
40			analysis plan can be found, if not in the protocol	
41				
42				
43	Statistics: additional	#20b	Methods for any additional analyses (eg, subgroup and adjusted	14
44	analyses		analyses)	
45				
46				
47	Statistics: analysis	#20c	Definition of analysis population relating to protocol non-	14
48	population and missing		adherence (eg, as randomised analysis), and any statistical	
49	data		methods to handle missing data (eg, multiple imputation)	
50				
51				
52	Methods: Monitoring			
53				
54				
55	Data monitoring:	#21a	Composition of data monitoring committee (DMC); summary of	20
56	formal committee		its role and reporting structure; statement of whether it is	
57			independent from the sponsor and competing interests; and	
58				
59				
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1		reference to where further details about its charter can be found,	
2		if not in the protocol. Alternatively, an explanation of why a	
3		DMC is not needed	
4			
5	Data monitoring:	#21b Description of any interim analyses and stopping guidelines,	20
6	interim analysis	including who will have access to these interim results and make	
7		the final decision to terminate the trial	
8			
9			
10			
11	Harms	#22 Plans for collecting, assessing, reporting, and managing solicited	12
12		and spontaneously reported adverse events and other unintended	
13		effects of trial interventions or trial conduct	
14			
15			
16	Auditing	#23 Frequency and procedures for auditing trial conduct, if any, and	NA
17		whether the process will be independent from investigators and	
18		the sponsor	
19			
20			
21	Ethics and		
22	dissemination		
23			
24			
25	Research ethics	#24 Plans for seeking research ethics committee / institutional	5
26	approval	review board (REC / IRB) approval	
27			
28			
29	Protocol amendments	#25 Plans for communicating important protocol modifications (eg,	6
30		changes to eligibility criteria, outcomes, analyses) to relevant	
31		parties (eg, investigators, REC / IRBs, trial participants, trial	
32		registries, journals, regulators)	
33			
34			
35			
36	Consent or assent	#26a Who will obtain informed consent or assent from potential trial	7
37		participants or authorised surrogates, and how (see Item 32)	
38			
39			
40	Consent or assent:	#26b Additional consent provisions for collection and use of	NA
41	ancillary studies	participant data and biological specimens in ancillary studies, if	
42		applicable	
43			
44			
45	Confidentiality	#27 How personal information about potential and enrolled	10;12
46		participants will be collected, shared, and maintained in order to	
47		protect confidentiality before, during, and after the trial	
48			
49			
50	Declaration of interests	#28 Financial and other competing interests for principal	19
51		investigators for the overall trial and each study site	
52			
53			
54	Data access	#29 Statement of who will have access to the final trial dataset, and	19
55		disclosure of contractual agreements that limit such access for	
56		investigators	
57			
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1	Ancillary and post trial	#30	Provisions, if any, for ancillary and post-trial care, and for	16
2	care		compensation to those who suffer harm from trial participation	
3				
4				
5	Dissemination policy:	#31a	Plans for investigators and sponsor to communicate trial results	20
6	trial results		to participants, healthcare professionals, the public, and other	
7			relevant groups (eg, via publication, reporting in results	
8			databases, or other data sharing arrangements), including any	
9			publication restrictions	
10				
11				
12				
13	Dissemination policy:	#31b	Authorship eligibility guidelines and any intended use of	19;20
14	authorship		professional writers	
15				
16				
17	Dissemination policy:	#31c	Plans, if any, for granting public access to the full protocol,	20
18	reproducible research		participant-level dataset, and statistical code	
19				
20				
21	Appendices			
22				
23	Informed consent	#32	Model consent form and other related documentation given to	25;26;27;28
24	materials		participants and authorised surrogates	
25				
26				
27	Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of	NA
28			biological specimens for genetic or molecular analysis in the	
29			current trial and for future use in ancillary studies, if applicable	
30				
31				

Notes:

- 34 • 18a: 10;11;12;13
- 35 • 18b: 10;11;12;13
- 36 • 32: 25;26;27;28 The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution
- 37 License CC-BY-ND 3.0. This checklist was completed on 24. July 2020 using
- 38 <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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