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Balloon tibioplasty vs ORIF for the treatment of Schatzker II-IV Tibial Plateau Fractures : a study protocol of randomised controlled trial

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Title: **Balloon tibioplasty vs ORIF for the treatment of Schatzker II-IV Tibial Plateau Fractures : a study protocol of randomised controlled trial**

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Abstract

Introduction: Balloon tibioplasty as an emerging technology, and has shown its advantages on recovering the depression of the articular surface. However, the clinical outcomes of balloon tibioplasty and ORIF are insufficient. This is the first randomised study to compare balloon tibioplasty against traditional ORIF and will provide guidance for treating patients with schatzker II-IV tibial plateau fractures.

Methods and analysis: A blinded randomised controlled trial will be conduct and a total of 100 participants with schatzker II-IV tibial plateau fracture will be randomly divided to either the balloon tibioplasty group or the ORIF group at a ratio of 1:1. The primary clinical outcome measures are the knee functional scores and the percentage of satisfactory recovered joint area. Secondary clinical outcome measures are intraoperative blood loss, operation time, VAS scores after surgery, length of hospital stay after surgery, fracture healing time and complications.

Ethics and dissemination: This study has been reviewed and approved by the Institutional Review Board of the Second Affiliated Hospital of Wenzhou Medical University (batch: 2017-12). The results will be presented in peer-reviewed journals after completion of the study.

Trial registration number: NCT03327337，Pre-results

Introduction

Tibial plateau fractures are complex intra-articular and metaphyseal lesions, accounting for 1-2% of all fractures[1], caused by either a valgus or varus force in combination with axial force[2]. The acknowledged operative indication was depressed fragments greater than 10 mm or instability >10° in a fully extended knee[3]. Many classification systems have been developed for tibial plateau fractures and used for preoperative planning and prognosis[4]. The Schatzker classification system is rather simple and widely used among orthopaedic surgeons in clinical practice. Schatzker II-IV tibial plateau fractures includes lateral or medial depressed articular fragments, the loss of joint congruity in these injuries has been shown to carry a poor prognosis such as posttraumatic arthrosis and valgus deformity despite proper management, so restoration of the joint surface is the goal of surgery[5-7]. The traditional ORIF treatment has a series of demerits, for instance, too much damage, the limited exposure of articular cavity, the insufficient diagnosis and treatment for the internal joint injury[8].

In recent years, with the development of technology, the treatment concept of tibial plateau fractures has developed from original mechanical fixation to biomechanical fixation and minimally invasive surgical[9], borrowing from the successful vertebral kyphoplasty technique, scholars put forward arthroscopic assisted balloon tibioplasty[10], a novel minimally invasive technique for the reduction of depressed tibial plateau fractures. Balloon tibioplasty as an emerging technology, which aims to visualize the articular surface and use balloon distension tibial plasty assisted by arthroscope to recover the depression of the articular surface, and then fixed the fracture according to patient's specific fracture type[11]. This technology has shown its advantages on recovering the depression of the articular surface[12], treating additional intraarticular lesions during the operation, and minimizing surgical trauma. Furthermore, under fluoroscopic, optimal centering of the expanding tibioplasty balloon allows a widespread and continuously increasing reduction force to the fracture area[13]. However, there are some factors influencing the clinical promotion of this sugical technique, for example, the application time of this sugical technique is short, the large number of case data and long-term follow-up is lacking, and the cost of operation is higher than tranditional ORIF[14].

Esmat Elabjer et al[15] examined the outcomes of arthroscopically-assisted reduction and internal fixation (ARIF) vs ORIF for the teartment of Schatzker I–III tibial plateau fractures, they showed that ARIF has a statistically significant less duration of hospital stay, both ARIF and ORIF can provide good results, in addition ARIF offer a more precise evaluation and treatment of associated intraarticular lesions. Ollivier et al[16] showed that the use of balloon guided inflation tibioplasty with injection of a resorbable bone substitute is safe, and results in a high rate of anatomic reduction and good clinical outcomes in patients with depressed tibial plateau fractures.

As we all know, no randomised controlled study of the clinical outcomes of balloon tibioplasty vs ORIF has been performed and high-quality RCTs are often deemed to be the gold standard for clinical research. In this study, we will perform an RCT to compare balloon tibioplasty and traditional ORIF.

Methods and design

This study is approved by the Institutional Ethics Review Board of the Second Affiliated Hospital of Wenzhou Medical University and conforms to the Declaration of Helsinki. All the patients provided informed consent to participate in this study. This trial has been registered at the US National Institutes of Health Clinical Trials Registry: NCT03327337. The protocol conforms to the Standard Protocol Items Recommendations for Interventional Trials. Figure 1 provides the chart of the trial design.

Participants

This study is a parallel group RCT conducted at the department of orthopaedics, the Second Affiliated Hospital of Wenzhou Medical University. The diagnosis of tibial plateau fracture was made on AP and lateral X-rays, CT scan was used to classify it.

Inclusion criteria

(1) fresh closed fracture, X-ray and CT scan showing Schatzker type II-IV tibial plateau fracture

(2) no history of knee-joint dislocation or other knee trauma
(3) no previous surgery on the knee
(4)the informed consent form signed
(5) age from 18 to 80 years

Exclusion criteria

(1)other types(Schatzker type I,V, and VI) of tibial plateau fracture
(2)open fractures, pathological fractures, immunodeficiency, hematological diseases and severe hepatorenal disorders
(3) the informed consent form unsigned

Randomisation and blinding

Pre-randomisation eligibility checks will be carried out to ensure that participants are eligible for study inclusion. A computerised randomisation was performed and the participants were divided into two groups by a sealed envelope: one group was treated with balloon tibioplasty and the other with ORIF. The patient and trial statistician were blinded until the last questionnaires have been completed.

Interventions

Balloon tibioplasty group:

Preoperative preparation: After the success continuous epidural anesthesia, the patients were placed in supine position with elevation of the affected knee slightly flexed at 45 degrees. T he conventional arthroscopic approach was used to checked the patient's joint cavity carefully and hemorrhage was removed , and combined ligament injury was explored. If combined with anterior or posterior cruciate ligament injury, we would reconstruct the ligament firstly.

Step 1: If there is a splitting tibial plateau fracture, an incision would be made in proximal tibia according to the fracture type.A small locking T-plate would be placed using minimally invasive techniques, then a temporary cortical bone screw would be pre-placed for prevention of cortical rupture when the balloon was enlarged. The temporary fixation of cortical bone screw permitted further adjustment on the position of the plate. If there is no splitting tibial plateau fracture , proceed to step 2 directly.

Step 2: 3 kirschner wires were placed under fluoroscopy on a surface locating below the depressed fragments. The suitable position for placing the balloon was predetermined under fluoroscopy. Then the surgeon gradually inflated the balloon with contrast solution and elevated the fragment till it was visually anatomically reducted on a true AP fluoroscopic view. Then the arthroscope was used to make sure the anatomically reduction. If not, the balloon would be deflated, repositioned, and re-inflated to reduce the persistent depression. After balloon removal, we careffy injected calcium phosphate cement to the balloon-created cavity under fluoroscopic, making sure no excessive cement overflowed into the tibial medullary cavity. We took out the 3 kirschner wires ,inserted the rest screws,and finally sutured the incision.

ORIF group:

Preoperative preparation: After the success continuous epidural anesthesia, the patients were placed in supine position with elevation of the affected knee slightly

flexed at 45 degrees. The patients were treated with traditional Open Reduction and Internal Fixation(ORIF) and bone graft.

The patients were allowed to bear no weight within 4 weeks. 6-8 weeks after the operation, the patients were allowed to walk with sticks until the fracture was completely healed.

Outcome measurements

Primary Outcome Measure:

1.The knee functional scores after surgery will be assessed by the Rasmussen scores of knee function. The Rasmussen scores will be recorded at 1、2、3、6、12 and 24 mouths postoperatively.

2.The percentage of satisfactory recovered joint area after operation will be assessed by the CT scan at 1、2、3、6、12 and 24 mouths postoperatively.

Secondary Outcome Measures:

1.The Intraoperative blood loss will be recorded in the anesthesia records, which included the blood in suction bottles (after subtracting the lavage fluid used during the surgery) and in weighed sponges that were used during the operation.

2.Operation time.

3.The pain degree of lower limb after surgery will be assessed by the VAS scores. The scores of VAS of leg pain will be recorded from operation day to leave hospital day(up to 2 weeks).

4. length of hospital stay after surgery.

5.Fracture healing time.

6.complications.

Follow-up

Follow-up will be conducted at 1,2,3,6,12 and 24 months postoperatively.

Monitoring

All investigators who have completed training could independently collect the data and assess the clinical outcomes. Safety and data monitoring will be performed periodically during the study. All paper and electronic data will be stored for 10 years in the secure research archives at the Second Affiliated Hospital of Wenzhou Medical University with restricted access.

Sample size

In order to pilot this study, the investigators have decided to recruit 50 patients into each arm of the trial and allow for a dropout rate of 20% for an effective sample size of 40 patients in each arm. The sample size is considered adequate to verify the research hypothesis.

Statistical analysis

The trial data will be calculated by the SPSS V.19.0 software. Differences in the operative time and intraoperative blood loss, the percentage of joint area recovered satisfactory, and complications between 2 groups will be analysed by two independent-samples t-tests. VAS scores and Rasmussen scores will be analysed by a repeated-measures analysis of variance. Changes in the data between different follow-up time points and the baseline will also be calculated, and the changes in data between 2 groups will be assessed by two independent-samples t-tests.

Discussion

Ideal treatment of schatzker II-IV tibial plateau fracture not only has to achieve anatomical restoration of joint surface to prevent cartilage damage and post-traumatic arthritis, but also rigid fixation to allow early post-operative rehabilitation[17]. Balloon tibioplasty is reported as a minimally invasive technique, which creating a symmetric, contained defect to hold a bone filler for subchondral support, and the balloon allows access to the posterior compressions while eliminating the neurological and vascular risks of a conventional approach[14]. This technique has already been used for kyphoplasty and maxillofacial surgery, and recently used for tibial plateau fractures[18]. This paper describes the protocol for conducting an RCT in China that will investigate the efficacy of balloon tibioplasty in treating schatzker II-IV tibial plateau fractures. In this trial, we designed a ORIF group as a controlled group to identify the clinical outcomes of schatzker II-IV tibial plateau fractures with balloon tibioplasty fixation. It is hypothesised that balloon tibioplasty, compared with ORIF, is superior in reducing disability and thus has a better clinical outcome. This study is the first RCT to compare schatzker II-IV tibial plateau fractures with balloon tibioplasty against traditional ORIF in china. In the case that our hypothesis is confirmed, our consequences will have an important value in the schedule and development of treatment options in schatzker II-IV tibial plateau fractures surgery. We anticipate that the results will provide more reliable evidence and clarify the value of balloon tibioplasty as a treatment for patients with schatzker II-IV tibial plateau fractures.

Contributors

Ji-Qi Wang helped to design the trial and wrote the manuscript. Bing-Jie Jiang helped to design the trial. Wei-Jun Guo helped to conceive the trial and revised the manuscript. Wei-Jiang Zhang recruit the patients and conduct the trial. A-Bing Li will planned the statistical analysis. You-Ming Zhao helped to design the study and critically revised the manuscript. All authors read and approved the final manuscript.

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The funders had no role in the design, execution or writing of the study.

Competing interests

None declared.

Patient consent

Obtained.

Ethics approval

The study had been reviewed and approved by the ethics committee of the Second Affiliated Hospital of the Wenzhou Medical University, Wenzhou, China (batch: 2017-12).

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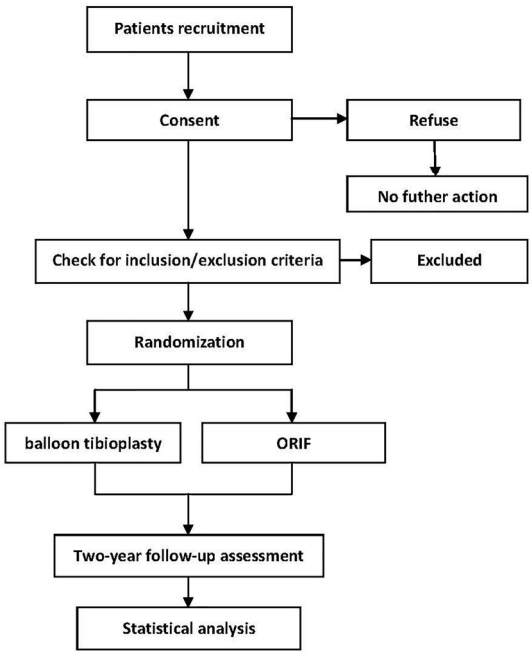
Figure 1. Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.



Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.

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Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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Keywords: Tibial plateau fracture; Arthroscopic-assisted surgery; Balloon tibioplasty; Open Reduction Internal Fixation; Protocol

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Abstract

Introduction: Arthroscopic-assisted balloon tibioplasty is an emerging technology that has shown advantages in recovering depression of the articular surface. However, arthroscopic-assisted balloon tibioplasty does not produce sufficiently beneficial clinical outcomes. This is the first randomized study to compare arthroscopic-assisted balloon tibioplasty with traditional open reduction internal fixation (ORIF), and will provide guidance for treating patients with Schatzker II–IV tibial plateau fractures.

Methods and analysis: A blinded randomized controlled trial will be conducted and a total of 80 participants with Schatzker II–IV tibial plateau fracture will be randomly divided into either the arthroscopic-assisted balloon tibioplasty group or the ORIF group, at a ratio of 1:1. The primary clinical outcome measures are the knee functional scores, Rasmunssen radiological evaluation scores, and the quality of reduction based on postoperative computed tomography scan. Secondary clinical outcome measures are intraoperative blood loss, surgical duration, visual analog scale score after surgery, hospital duration after surgery, complications, and SF-36 score.

Ethics and dissemination: This study has been reviewed and approved by the Institutional Review Board of the Second Affiliated Hospital of Wenzhou Medical University (batch: 2017-12). The results will be presented in peer-reviewed journals after completion of the study.

Trial registration number: NCT03327337, Pre-results

Strengths and limitations of this study: This trial is designed to have a feasible, comparative effectiveness trial design that has similarities to common clinical situations. This study is the first RCT to compare the outcomes of Schatzker II–IV tibial plateau fractures between arthroscopic-assisted balloon tibioplasty and traditional ORIF in China. The size of the study sample limits the power of the observations.

Introduction

Tibial plateau fractures are complex intraarticular and metaphyseal lesions, accounting for 1–2% of all fractures [1] caused by either a valgus or varus force in combination with an axial force [2]. The acknowledged surgical indication for a tibial plateau fracture is tilt or valgus malalignment exceeding 5°, articular step-off exceeding 3 mm, or condylar widening exceeding 5 mm (lateral tibial plateau fracture), or tilt or any displacement (medial tibial plateau fracture) [3]. Many classification systems have been developed for tibial plateau fractures and are used for preoperative planning and prognostic purposes [4-6]. The Schatzker classification system is simple and widely used among orthopedic surgeons in clinical practice. Schatzker II–IV tibial plateau fractures include lateral or medial depressed articular fragments, and loss of joint congruity in these injuries is associated with a poor prognosis, such as posttraumatic arthrosis and valgus deformity despite proper management. Therefore, restoration of the joint surface is the goal of surgery [7-9].

Open reduction internal fixation (ORIF) for treatment of this type of fracture has yielded promising results. Gavaskar *et al.* [10] reported that ORIF could achieve satisfactory radiological and functional results in split depression lateral tibial plateau fractures. After ORIF for 15 cases of medial tibial plateau fractures, Morin *et al.* [11] reported that 93% of patients were satisfied or very satisfied with their functional recovery and there were no cases of pseudarthrosis or secondary varus displacement. However, traditional ORIF treatment has a number of disadvantages, e.g., excessive damage, limited exposure of the articular cavity, and insufficient ability to diagnose and address internal joint injury [12].

With recent technological advances, the treatment concept of tibial plateau fractures has progressed from mechanical fixation to minimally invasive surgical interventions for biomechanical stability [13,14]. Based on the success of vertebral kyphoplasty, arthroscopic assisted balloon tibioplasty [15] has been developed as a novel minimally invasive technique for reducing depressed tibial plateau fractures. Arthroscopic-assisted balloon tibioplasty is an emerging technology that aims to visualize the articular surface, and uses balloon distension tibial plasty assisted by arthroscopy to recover depression of the articular surface and fix the fracture according to its specific type [16]. This technology has shown advantages in recovering depression of the articular surface [17], treating additional intraarticular lesions during the operation, and minimizing surgical trauma. Furthermore, under fluoroscopy, optimal centering of the expanding tibioplasty balloon allows a widespread and continuously increasing reduction force to be applied to the fracture area [18]. Primary data from Ollivier *et al.* [19] showed that depressed tibial plateau fractures treated with arthroscopic-assisted balloon tibioplasty had a high rate of anatomic reduction and good clinical outcomes. Similar results were also reported by Pizanis *et al.* [15] using arthroscopic-assisted balloon tibioplasty without classic fenestration of the tibia, which would minimize surgical trauma. However, a number of factors influence the clinical adoption of this surgical technique: the application time of is short, there is a paucity of case data and information regarding long-term follow-up, and the cost of operation is higher than traditional ORIF [20].

To our knowledge, there have been no randomized controlled trials (RCTs) of the clinical outcomes of arthroscopic-assisted balloon tibioplasty versus ORIF, where high-quality RCTs are generally deemed to be the gold standard in clinical research. In this study, we will perform an RCT to compare arthroscopic-assisted balloon tibioplasty and traditional ORIF.

Methods and design

This study has been approved by the Ethics Committee of the Second Affiliated Hospital of Wenzhou Medical University, and conforms to the Declaration of Helsinki. All patients will provide informed consent prior to participation in this study. This trial has been registered at the US National Institutes of Health Clinical Trials Registry (NCT03327337). The protocol conforms to the Standard Protocol Items Recommendations for Interventional Trials. Figure 1 shows a chart of the trial design.

Participants

This study is a parallel group RCT conducted at the Department of Orthopaedics, the Second Affiliated Hospital of Wenzhou Medical University. Fractures will be evaluated on anteroposterior (AP) and laterolateral (LL) radiographs and by computed tomography (CT), which can analyze the fracture pattern more precisely.

Inclusion criteria

(1) Acute closed fractures less than 10 days old, and X-ray and CT scan showing Schatzker type II, III or IV with depression of the medial tibial plateau only. (supplementary information, S1)

(2) No history of knee joint dislocation or other knee trauma.

(3) Signed informed consent.

(4) Age of 18–80 years.

Exclusion criteria

(1) Other types of tibial plateau fracture (Schatzker type I, IV with split or comminute fracture, V, and VI).

(2) Concomitant injuries that will interfere with functional recovery, such as combined fracture of the lower limb.

(3) Open fractures, pathological fractures, immunodeficiency, hematological diseases, or severe hepatorenal disorders.

Patient involvement

The design of this study was not directly involved in the patients, and the intervention in this study is not considered to change the patient's direct perception of the preoperative and intraoperative processes or the postoperative rehabilitation therapy. As the enrolment in study may influence the patient's view of the clinical work or even feel like a burden, the patients will be interviewed randomly to identify adverse effects. The results will be informed by mail to all the patients involved.

Randomization and blinding

Pre-randomization eligibility checks will be carried out to ensure that participants are eligible for inclusion in the study. Patients will be randomly assigned to one of two groups (experimental or control) using a computer-generated random assignment in a 1:1 ratio, and allocation will be concealed until the point of randomization. Patients, researchers performing the follow-up measurements, and the trial statistician will be blinded to the group allocations until the last questionnaires have been completed.

Interventions

Arthroscopic-assisted balloon tibioplasty group:

Step 1: In cases with a splitting tibial plateau fracture (Schatzker type II), an incision will be made in the proximal tibia according to the fracture type, for placement of a small locking T-plate (Synthes, Freiburg, Germany) using minimally invasive techniques. Then, a temporary cortical

bone screw will be inserted to prevent cortical rupture when the balloon is enlarged. Temporary fixation of the cortical bone screw will permit further adjustment of the position of the plate. In cases with no splitting tibial plateau fracture (Schatzker type III or IV with depression of the medial tibial plateau only), we will proceed to step 2 directly.

Step 2: Three Kirschner wires (2 mm) will be placed below the depressed fragment under fluoroscopy. Using live fluoroscopy, the balloon will be placed in the optimal position and slowly inflated with contrast solution (Ultravist®; Schering, Berlin, Germany). The arthroscope will then be used to confirm anatomical reduction of the depressed fragment. The balloon will be deflated, repositioned, and reinflated to reduce the persistent depression. After removal of the balloon, we will use a Kirschner wire (2 mm) to temporarily lift the depressed fragment and carefully inject calcium phosphate cement (Osteopal® V; Heraeus Medical GmbH, Wehrheim, Germany) into the cavity produced by the balloon under fluoroscopic guidance, ensuring there is no excessive cement overflow into the tibial medullary cavity. (supplementary information, S2)

ORIF group:

For this technique, a lateral or medial surgical approach will be used according to the type of fracture. The depressed fragment will be elevated by a metal tamp through a small cortical window in the proximal tibia, and bone substitute will be used. Finally, internal fixation will be performed when an acceptable reduction has been achieved.

If satisfactory reduction cannot be achieved using arthroscopic-assisted balloon tibioplasty, patients will undergo ORIF and be excluded from the study. All patients will receive rehabilitation therapy regardless of the group to which they are allocated, and progressive partial weight-bearing will be permitted with the aid of two crutches. Postoperative CT scans will be performed immediately, and at 2 weeks and 1, 3, 6, 12, and 24 months, and Rasmunssen radiological evaluation will be performed [21]. To evaluate functional recovery of the knee joint and health-related quality of life, all patients will complete Rasmussen functional score and Short-Form Health Survey (SF-36) questionnaires during the follow-up period. Scoring will performed by two researchers who not involved in the initial treatment.

Outcome measurements

Primary outcome measure:

1. Knee functional recovery will be assessed by the Rasmussen functional score, which will be recorded at 3, 6, 12, and 24 months postoperatively.
2. Rasmunssen radiological evaluation will be recorded immediately, and at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.
3. The quality of reduction will be determined based on postoperative CT scans, which can directly measure the amount of residual depression, at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.

Secondary outcome measures:

1. Intraoperative blood loss will be recorded in the anesthesia records, and will include the blood in suction bottles (after subtracting the lavage fluid used during the surgery), and that in the weighed sponges used during the operation.
2. Surgical duration.
3. The severity of lower limb pain after surgery will be assessed using a visual analog scale (VAS) pain score. The VAS scores of leg pain will be recorded from the day of the operation to the day of discharge from hospital (up to 2 weeks).

4. Hospitalization period after surgery.

5. Complications including wound infection (defined as minor, major, early, or late according to the criteria described by the Surgical Infection Study Group [22]), reoperations, and posttraumatic arthritis (PTA) will be recorded.

PTA may not be seen in patients within the 24-month follow-up period, and we will perform follow-up for at least 10 years in all patients.

6. Health-related quality of life will be measured using the Short-Form Health Survey (SF-36) questionnaire during follow-up.

The SF-36 is a health-related quality of life questionnaire used to assess both the mental and physical health of the patient.

Baseline demographics

Sex, age, body mass index (BMI), mechanism of injury, smoking status, alcohol use, and comorbidities (i.e., hypertension, diabetes, cardiopathy)

Follow-up

Follow-up will be conducted at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.

Monitoring

All investigators who have completed training are capable of independently collecting the data and assessing the clinical outcomes, and all electronic data will be recorded by an electronic data capture system (DAP Software Company, Beijing, China). Safety and data monitoring will be performed periodically during the study. All paper and electronic data will be stored for 10 years in the secure research archives at the Second Affiliated Hospital of Wenzhou Medical University, with restricted access.

Sample size calculation

There have been no previous studies on which to base the sample size calculation. In a related study [21], the excellent Rasmunssen radiological evaluation proportion of the control group was 60%, and the proportion of the intervention group was 70%. We carried out power analysis to determine the sample size required to show safety with a type I error probability of 5% and an 80% probability of avoiding a type II error. Using these assumptions, the required sample size is 35 per group. With the assumption of a 12.5% loss to follow-up, we will include 40 participants per group.

Statistical analysis

The trial data will be analyzed using SPSS for Windows software (ver. 19.0; SPSS Inc., Chicago, IL). For continuous variables, the Shapiro–Wilk test will be applied to determine if they follow a normal distribution. For normally distributed variables, the means will be calculated and compared using the independent samples *t* test (Student's *t* test); otherwise, the Mann–Whitney U test will be used for group comparisons. The chi-square test will be used to analyze qualitative variables. In all analyses, $P < 0.05$ will be taken to indicate statistical significance.

Discussion

There have been a number of reports describing treatment for tibial plateau fractures. In a systematic review of the treatment of tibial plateau fractures, Metcalfe *et al.* [23] suggested that ORIF and external fixation are both acceptable strategies for managing bicondylar tibial plateau fractures, with no statistically significant differences found in the rates of complications between the two methods. In addition, after a systematic review of all studies reporting return to sport following tibial plateau fracture, Robertson *et al.* [24] reported that the rate of return to sport for

the total cohort was 70%, versus 60% for those with fractures managed with ORIF and 83% for fractures treated with arthroscopic-assisted reduction internal fixation (OR 3.22, 95% CI: 2.09–4.97, $P < 0.001$).

An ideal treatment method for Schatzker II–IV tibial plateau fracture not only has to achieve anatomical restoration of the knee joint, but also rigid fixation to allow early postoperative rehabilitation [25]. Traditional ORIF requires extensive soft tissue dissection, which may lead to numerous negative outcomes such as slow wound healing, infection, and PTA [26]. Due to limited exposure, intraarticular lesions, such as meniscus or anterior cruciate ligament (ACL) injuries, cannot be diagnosed and treated properly [27]. Ruffolo *et al.* [28] reported that nonunion and deep infections occur commonly after ORIF, and long surgical durations are associated with higher rates of infection. With the development of arthroscopic techniques, arthroscopy-assisted reduction and internal fixation (ARIF) has been widely adopted in the treatment of tibial plateau fractures [29], and has shown good functional recovery and radiological results [30-32]. After comparing the Rasmussen and Hospital for Special Surgery knee-rating (HSS) scores between ARIF and ORIF, Dall'oca *et al.* [12] reported that the ARIF technique improved the clinical outcome in Schatzker type II–IV fractures. Balloon tibioplasty is an arthroscopic-assisted minimally invasive technique that creates a symmetrical, contained defect to hold bone filler for subchondral support; the balloon also allows eliminate the neurological and vascular risks of the conventional approach[20]. This technique has already been used for kyphoplasty and maxillofacial surgery, and has recently been applied for tibial plateau fractures [15,19,33]. Mauffrey *et al.* [20] reported early positive results with arthroscopy-assisted balloon tibioplasty used as an alternative reduction method, and the method is gaining in acceptance. This paper describes the protocol for conducting an RCT in China that will investigate the efficacy of arthroscopic-assisted balloon tibioplasty in treating Schatzker II–IV tibial plateau fractures. The design of this trial included an ORIF group as a control group, to compare the clinical outcomes of Schatzker II–IV tibial plateau fractures with those of arthroscopic-assisted balloon tibioplasty fixation. Arthroscopic-assisted balloon tibioplasty is hypothesized to be superior in reducing surgical trauma, and to have better clinical outcomes in comparison with ORIF. This study is the first RCT to compare the outcomes of Schatzker II–IV tibial plateau fractures between arthroscopic-assisted balloon tibioplasty and traditional ORIF in China. If our hypothesis is confirmed, our results will be important for informing the scheduling and development of treatment options for Schatzker II–IV tibial plateau fracture surgery. We anticipate that the results will provide reliable evidence and clarify the value of arthroscopic-assisted balloon tibioplasty as a treatment for patients with Schatzker II–IV tibial plateau fractures.

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Contributors

Ji-Qi Wang helped to design the trial and wrote the manuscript. Bing-Jie Jiang helped to design the trial. Wei-Jun Guo helped to conceive the trial and revised the manuscript. Wei-Jiang Zhang recruit the patients and conduct the trial. A-Bing Li will planned the statistical analysis. You-Ming Zhao helped to design the study and critically revised the manuscript. All authors read and approved the final manuscript.

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The funders had no role in the design, execution or writing of the study.

Competing interests

None declared.

Patient consent

Obtained.

Ethics approval

The study had been reviewed and approved by the ethics committee of the Second Affiliated Hospital of the Wenzhou Medical University, Wenzhou, China (batch: 2017-12).

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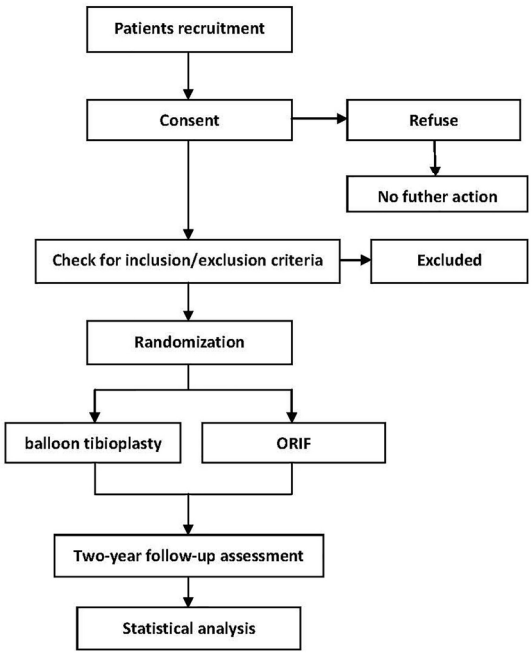
Figure 1. Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.



Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.

189x170mm (300 x 300 DPI)

supplementary information

title: Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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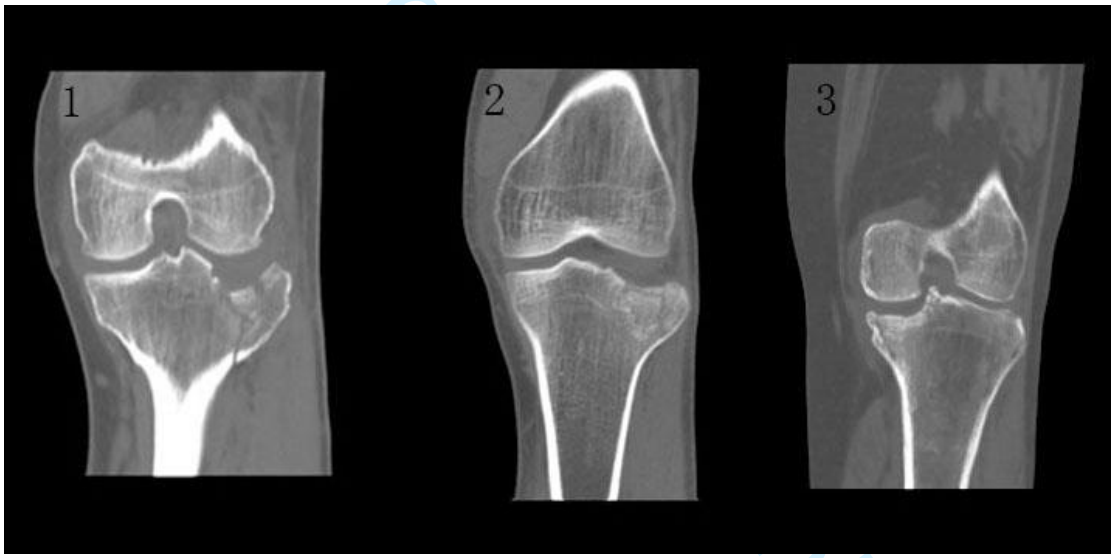
supplementary information, S1

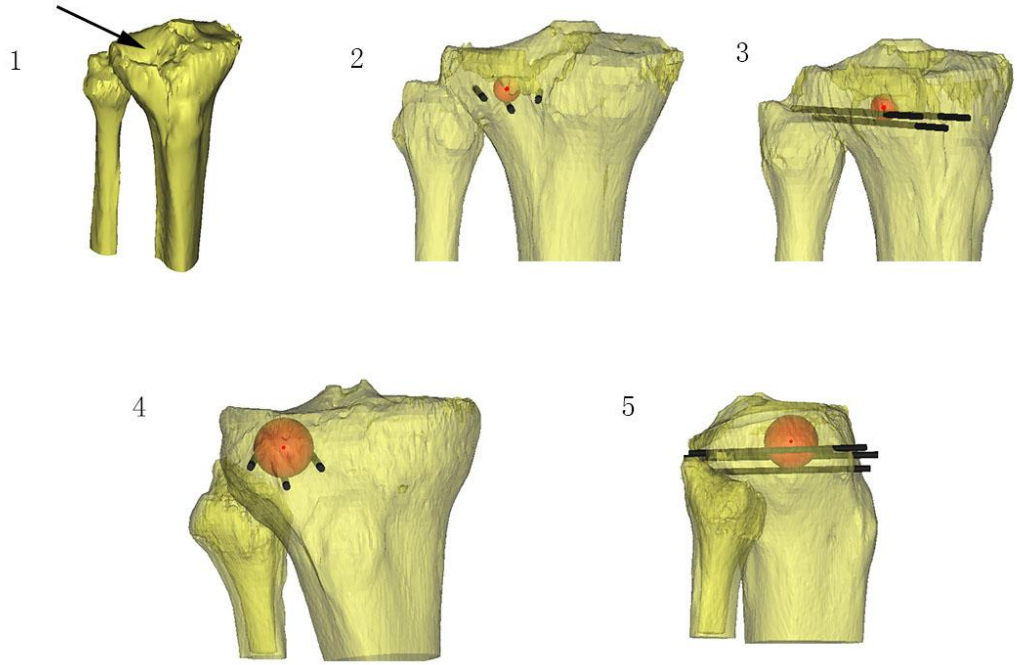
CT scan of Schzatzker II to IV tibial plateau fractures, which conform to our inclusion criteria.



1, CT scan of Schzatzker II tibial plateau fracture, which include the lateral platform split and depression (left limb); 2, CT scan of Schzatzker III tibial plateau fracture, which only include the lateral tibial plateau depression (left limb); 3, CT scan of Schzatzker IV tibial plateau fracture, which only include the medial tibial plateau depression (left limb).

supplementary information, S2

Simulated the operation process of Schzatzker III tibial plateau fracture with Mimics software



1, The black arrowhead in the figure points to the depression of the lateral tibial plateau; 2, Three Kirschner wires and the balloon are placed below the depressed fragment under fluoroscopy (anteroposterior); 3, Three Kirschner wires and balloon are placed below the depressed fragment under fluoroscopy (laterolateral); 4, The balloon slowly inflated with contrast solution, and the depression of the lateral tibial plateau will be anatomical reduction (anteroposterior); 5, The balloon slowly inflated with contrast solution, and the depression of the lateral tibial plateau will be anatomical reduction (laterolateral). After removal of the balloon, calcium phosphate cement will injected into the cavity produced by the balloon under fluoroscopic guidance, ensuring there is no excessive cement overflow into the tibial medullary cavity.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description
Administrative information		
Title (P1)	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration (P1)	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version (Not mentioned)	3	Date and version identifier
Funding (P7)	4	Sources and types of financial, material, and other support
Roles and responsibilities (P6)	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	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
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale (P2)	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
	6b	Explanation for choice of comparators
Objectives (P6)	7	Specific objectives or hypotheses

Trial design (P2)	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting (P2)	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
Eligibility criteria (P3)	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions (P3-P4)	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	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)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes (P4-P5)	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline (P3)	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size (P5)	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment (P5)	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation (P3)	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism (P3)	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation (P3)	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking) (P3)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods (P4)	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management (P5)	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods (P5)	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

Data monitoring (P5)	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms (P5)	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing (P5)	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval (P6)	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments (Not mentioned)	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent (P7)	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality (P5)	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests (P7)	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data (P5)	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care (Not mentioned)	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy (P5)	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials (Not mentioned)	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens (Not applicable)	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Sports and exercise medicine, Surgery
Keywords:	ORTHOPAEDIC & TRAUMA SURGERY, Knee < ORTHOPAEDIC & TRAUMA SURGERY, Adult orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY

Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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Keywords: Tibial plateau fracture; Arthroscopic-assisted surgery; Balloon tibioplasty; Open Reduction Internal Fixation; Protocol

Word count: 2467

Abstract

Introduction: Arthroscopic-assisted balloon tibioplasty is an emerging technology that has shown advantages in recovering depression of the articular surface. However, studies evaluating clinical outcomes between arthroscopic-assisted balloon tibioplasty and traditional open reduction internal fixation (ORIF) are sparse. This is the first randomized study to compare arthroscopic-assisted balloon tibioplasty with ORIF, and will provide guidance for treating patients with Schatzker type II, III and IV with depression of the medial tibial plateau only.

Methods and analysis: A blinded randomized controlled trial will be conducted and a total of 80 participants will be randomly divided into either the arthroscopic-assisted balloon tibioplasty group or the ORIF group, at a ratio of 1:1. The primary clinical outcome measures are the knee functional scores, Rasmunssen radiological evaluation scores, and the quality of reduction based on postoperative computed tomography scan. Secondary clinical outcome measures are intraoperative blood loss, surgical duration, visual analog scale score after surgery, hospital duration after surgery, complications, and SF-36 score.

Ethics and dissemination: This study has been reviewed and approved by the Institutional Review Board of the Second Affiliated Hospital of Wenzhou Medical University (batch: 2017-12). The results will be presented in peer-reviewed journals after completion of the study.

Trial registration number: NCT03327337, Pre-results

Article summary:

Strengths and limitations of this study:

This trial is designed to have a feasible, comparative effectiveness trial design that has similarities to common clinical situations.

This study is the first RCT to compare the outcomes of Schatzker II–IV tibial plateau fractures between arthroscopic-assisted balloon tibioplasty and traditional ORIF in China.

Our results may be limited by heterogeneity due to differences in age, gender, region and race.
The size of the study sample limits the power of the observations.
Risk of bias due to death, loss of follow -up or uncompliant patients unable to complete tests or questionnaires.

Introduction

Tibial plateau fractures are complex intraarticular and metaphyseal lesions, accounting for 1–2% of all fractures [1] caused by either a valgus or varus force in combination with an axial force [2]. The acknowledged surgical indication for a tibial plateau fracture is tilt or valgus malalignment exceeding 5°, articular step-off exceeding 3 mm, or condylar widening exceeding 5 mm (lateral tibial plateau fracture), or tilt or any displacement (medial tibial plateau fracture) [3]. Many classification systems have been developed for tibial plateau fractures and are used for preoperative planning and prognostic purposes [4-6]. The Schatzker classification system is simple and widely used among orthopedic surgeons in clinical practice. Schatzker II–IV tibial plateau fractures include lateral or medial depressed articular fragments, and loss of joint congruity in these injuries is associated with a poor prognosis, such as posttraumatic arthrosis and valgus deformity despite proper management. Therefore, restoration of the joint surface is the goal of surgery [7-9].

Open reduction internal fixation (ORIF) for treatment of this type of fracture has yielded promising results. Gavaskar *et al.* [10] reported that ORIF could achieve satisfactory radiological and functional results in split depression lateral tibial plateau fractures. After ORIF for 15 cases of medial tibial plateau fractures, Morin *et al.* [11] reported that 93% of patients were satisfied or very satisfied with their functional recovery and there were no cases of pseudarthrosis or secondary varus displacement. However, traditional ORIF treatment has a number of disadvantages, e.g., excessive damage, limited exposure of the articular cavity, and insufficient ability to diagnose and address internal joint injury [12].

With recent technological advances, the treatment concept of tibial plateau fractures has progressed from mechanical fixation to minimally invasive surgical interventions for biomechanical stability [13,14]. Based on the success of vertebral kyphoplasty, arthroscopic assisted balloon tibioplasty [15] has been developed as a novel minimally invasive technique for reducing depressed tibial plateau fractures. Arthroscopic-assisted balloon tibioplasty is an emerging technology that aims to visualize the articular surface, and uses balloon distension tibial plasty assisted by arthroscopy to recover depression of the articular surface and fix the fracture according to its specific type [16]. This technology has shown advantages in recovering depression of the articular surface [17], treating additional intraarticular lesions during the operation, and minimizing surgical trauma. Furthermore, under fluoroscopy, optimal centering of the expanding tibioplasty balloon allows a widespread and continuously increasing reduction force to be applied to the fracture area [18]. Primary data from Ollivier *et al.* [19] showed that depressed tibial plateau fractures treated with arthroscopic-assisted balloon tibioplasty had a high rate of anatomic reduction and good clinical outcomes. Similar results were also reported by Pizanis *et al.* [15] using arthroscopic-assisted balloon tibioplasty without classic fenestration of the tibia, which would minimize surgical trauma. However, a number of factors influence the clinical adoption of this surgical technique: the application time of is short, there is a paucity of case data and information regarding long-term follow-up, and the cost of operation is higher than traditional

ORIF [20].

To our knowledge, there have been no randomized controlled trials (RCTs) of the clinical outcomes of arthroscopic-assisted balloon tibioplasty versus ORIF, where high-quality RCTs are generally deemed to be the gold standard in clinical research. In this study, we will perform an RCT to compare arthroscopic-assisted balloon tibioplasty and traditional ORIF.

Methods and design

This study has been approved by the Ethics Committee of the Second Affiliated Hospital of Wenzhou Medical University, and conforms to the Declaration of Helsinki. All patients will provide informed consent prior to participation in this study. This trial has been registered at the US National Institutes of Health Clinical Trials Registry (NCT03327337). The protocol conforms to the Standard Protocol Items Recommendations for Interventional Trials. Figure 1 shows a chart of the trial design.

Participants

This study is a parallel group RCT conducted at the Department of Orthopaedics, the Second Affiliated Hospital of Wenzhou Medical University. Fractures will be evaluated on anteroposterior (AP) and laterolateral (LL) radiographs and by computed tomography (CT), which can analyze the fracture pattern more precisely.

Inclusion criteria

(1) Acute closed fractures less than 10 days old, and X-ray and CT scan showing Schatzker type II, III or IV with depression of the medial tibial plateau only. (supplementary information, S1)

(2) No history of knee joint dislocation or other knee trauma.

(3) Signed informed consent.

(4) Age of 18–80 years.

Exclusion criteria

(1) Other types of tibial plateau fracture (Schatzker type I, IV with split or comminute fracture, V, and VI).

(2) Concomitant injuries that will interfere with functional recovery, such as combined fracture of the lower limb.

(3) Open fractures, pathological fractures, immunodeficiency, hematological diseases, or severe hepatorenal disorders.

Patient involvement

The design of this study was not directly involved in the patients, and the intervention in this study is not considered to change the patient's direct perception of the preoperative and intraoperative processes or the postoperative rehabilitation therapy. As the enrolment in study may influence the patient's view of the clinical work or even feel like a burden, the patients will be interviewed randomly to identify adverse effects. The results will be informed by mail to all the patients involved.

Randomization and blinding

Pre-randomization eligibility checks will be carried out to ensure that participants are eligible for inclusion in the study. Patients will be randomly assigned to one of two groups (experimental or control) using a computer-generated random assignment in a 1:1 ratio, and allocation will be concealed until the point of randomization. Patients, researchers performing the follow-up measurements, and the trial statistician will be blinded to the group allocations until the last questionnaires have been completed.

Interventions

Arthroscopic-assisted balloon tibioplasty group:

Step 1: In cases with a splitting tibial plateau fracture (Schatzker type II), an incision will be made in the proximal tibia according to the fracture type, for placement of a small locking T-plate (Synthes, Freiburg, Germany) using minimally invasive techniques. Then, a temporary cortical bone screw will be inserted to prevent cortical rupture when the balloon is enlarged. Temporary fixation of the cortical bone screw will permit further adjustment of the position of the plate. In cases with no splitting tibial plateau fracture (Schatzker type III or IV with depression of the medial tibial plateau only), we will proceed to step 2 directly.

Step 2: Three Kirschner wires (2 mm) will be placed below the depressed fragment under fluoroscopy. Using live fluoroscopy, the balloon will be placed in the optimal position and slowly inflated with contrast solution (Ultravist®; Schering, Berlin, Germany). The arthroscope will then be used to confirm anatomical reduction of the depressed fragment. The balloon will be deflated, repositioned, and reinflated to reduce the persistent depression. After removal of the balloon, we will use a Kirschner wire (2 mm) to temporarily lift the depressed fragment and carefully inject calcium phosphate cement (Osteopal® V; Heraeus Medical GmbH, Wehrheim, Germany) into the cavity produced by the balloon under fluoroscopic guidance, ensuring there is no excessive cement overflow into the tibial medullary cavity. (supplementary information, S2)

ORIF group:

For this technique, a lateral or medial surgical approach will be used according to the type of fracture. The depressed fragment will be elevated by a metal tamp through a small cortical window in the proximal tibia, and bone substitute will be used. Finally, internal fixation will be performed when an acceptable reduction has been achieved.

If satisfactory reduction cannot be achieved using arthroscopic-assisted balloon tibioplasty, patients will undergo ORIF and be excluded from the study. All patients will receive rehabilitation therapy regardless of the group to which they are allocated, and progressive partial weight-bearing will be permitted with the aid of two crutches. Postoperative CT scans will be performed immediately, and at 2 weeks and 1, 3, 6, 12, and 24 months, and Rasmunssen radiological evaluation will be performed [21]. To evaluate functional recovery of the knee joint and health-related quality of life, all patients will complete Rasmussen functional score and Short-Form Health Survey (SF-36) questionnaires during the follow-up period. Scoring will performed by two researchers who not involved in the initial treatment.

Outcome measurements

Primary outcome measure:

1. Knee functional recovery will be assessed by the Rasmussen functional score, which will be recorded at 3, 6, 12, and 24 months postoperatively.
2. Rasmunssen radiological evaluation will be recorded immediately, and at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.
3. The quality of reduction will be determined based on postoperative CT scans, which can directly measure the amount of residual depression, at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.

Secondary outcome measures:

1. Intraoperative blood loss will be recorded in the anesthesia records, and will include the blood in suction bottles (after subtracting the lavage fluid used during the surgery), and that in the

weighed sponges used during the operation.

2. Surgical duration.

3. The severity of lower limb pain after surgery will be assessed using a visual analog scale (VAS) pain score. The VAS scores of leg pain will be recorded from the day of the operation to the day of discharge from hospital (up to 2 weeks).

4. Hospitalization period after surgery.

5. Complications including wound infection (defined as minor, major, early, or late according to the criteria described by the Surgical Infection Study Group [22]), reoperations, and posttraumatic arthritis (PTA) will be recorded.

PTA may not be seen in patients within the 24-month follow-up period, and we will perform follow-up for at least 10 years in all patients.

6. Health-related quality of life will be measured using the Short-Form Health Survey (SF-36) questionnaire during follow-up.

The SF-36 is a health-related quality of life questionnaire used to assess both the mental and physical health of the patient.

Baseline demographics

Sex, age, body mass index (BMI), mechanism of injury, smoking status, alcohol use, and comorbidities (i.e., hypertension, diabetes, cardiopathy)

Follow-up

Follow-up will be conducted at 2 weeks and 1, 3, 6, 12, and 24 months postoperatively.

Monitoring

All investigators who have completed training are capable of independently collecting the data and assessing the clinical outcomes, and all electronic data will be recorded by an electronic data capture system (DAP Software Company, Beijing, China). Safety and data monitoring will be performed periodically during the study. All paper and electronic data will be stored for 10 years in the secure research archives at the Second Affiliated Hospital of Wenzhou Medical University, with restricted access.

Sample size calculation

There have been no previous studies on which to base the sample size calculation. In a related study [21], the excellent Rasmunssen radiological evaluation proportion of the control group was 60%, and the proportion of the intervention group was 70%. We carried out power analysis to determine the sample size required to show safety with a type I error probability of 5% and an 80% probability of avoiding a type II error. Using these assumptions, the required sample size is 35 per group. With the assumption of a 12.5% loss to follow-up, we will include 40 participants per group.

Statistical analysis

The trial data will be analyzed using SPSS for Windows software (ver. 19.0; SPSS Inc., Chicago, IL). For continuous variables, the Shapiro–Wilk test will be applied to determine if they follow a normal distribution. For normally distributed variables, the means will be calculated and compared using the independent samples *t* test (Student's *t* test); otherwise, the Mann–Whitney U test will be used for group comparisons. The chi-square test will be used to analyze qualitative variables. In all analyses, $P < 0.05$ will be taken to indicate statistical significance.

Discussion

There have been a number of reports describing treatment for tibial plateau fractures. In a

systematic review of the treatment of tibial plateau fractures, Metcalfe *et al.* [23] suggested that ORIF and external fixation are both acceptable strategies for managing bicondylar tibial plateau fractures, with no statistically significant differences found in the rates of complications between the two methods. In addition, after a systematic review of all studies reporting return to sport following tibial plateau fracture, Robertson *et al.* [24] reported that the rate of return to sport for the total cohort was 70%, versus 60% for those with fractures managed with ORIF and 83% for fractures treated with arthroscopic-assisted reduction internal fixation (OR 3.22, 95% CI: 2.09–4.97, $P < 0.001$).

An ideal treatment method for Schatzker II–IV tibial plateau fracture not only has to achieve anatomical restoration of the knee joint, but also rigid fixation to allow early postoperative rehabilitation [25]. Traditional ORIF requires extensive soft tissue dissection, which may lead to numerous negative outcomes such as slow wound healing, infection, and PTA [26]. Due to limited exposure, intraarticular lesions, such as meniscus or anterior cruciate ligament (ACL) injuries, cannot be diagnosed and treated properly [27]. Ruffolo *et al.* [28] reported that nonunion and deep infections occur commonly after ORIF, and long surgical durations are associated with higher rates of infection. With the development of arthroscopic techniques, arthroscopy-assisted reduction and internal fixation (ARIF) has been widely adopted in the treatment of tibial plateau fractures [29], and has shown good functional recovery and radiological results [30-32]. After comparing the Rasmussen and Hospital for Special Surgery knee-rating (HSS) scores between ARIF and ORIF, Dall'oca *et al.* [12] reported that the ARIF technique improved the clinical outcome in Schatzker type II–IV fractures. Balloon tibioplasty is an arthroscopic-assisted minimally invasive technique that creates a symmetrical, contained defect to hold bone filler for subchondral support; the balloon also allows eliminate the neurological and vascular risks of the conventional approach[20]. This technique has already been used for kyphoplasty and maxillofacial surgery, and has recently been applied for tibial plateau fractures [15,19,33]. Mauffrey *et al.* [20] reported early positive results with arthroscopy-assisted balloon tibioplasty used as an alternative reduction method, and the method is gaining in acceptance. This paper describes the protocol for conducting an RCT in China that will investigate the efficacy of arthroscopic-assisted balloon tibioplasty in treating Schatzker II–IV tibial plateau fractures. The design of this trial included an ORIF group as a control group, to compare the clinical outcomes of Schatzker II–IV tibial plateau fractures with those of arthroscopic-assisted balloon tibioplasty fixation. Arthroscopic-assisted balloon tibioplasty is hypothesized to be superior in reducing surgical trauma, and to have better clinical outcomes in comparison with ORIF. This study is the first RCT to compare the outcomes of Schatzker II–IV tibial plateau fractures between arthroscopic-assisted balloon tibioplasty and traditional ORIF in China. If our hypothesis is confirmed, our results will be important for informing the scheduling and development of treatment options for Schatzker II–IV tibial plateau fracture surgery. We anticipate that the results will provide reliable evidence and clarify the value of arthroscopic-assisted balloon tibioplasty as a treatment for patients with Schatzker II–IV tibial plateau fractures.

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Contributors

Ji-Qi Wang helped to design the trial and wrote the manuscript. Bing-Jie Jiang helped to design

the trial. Wei-Jun Guo helped to conceive the trial and revised the manuscript. Wei-Jiang Zhang recruit the patients and conduct the trial. A-Bing Li will planned the statistical analysis. You-Ming Zhao helped to design the study and critically revised the manuscript. All authors read and approved the final manuscript.

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The funders had no role in the design, execution or writing of the study.

Competing interests

None declared.

Patient consent

Obtained.

Ethics approval

The study had been reviewed and approved by the ethics committee of the Second Affiliated Hospital of the Wenzhou Medical University, Wenzhou, China (batch: 2017-12).

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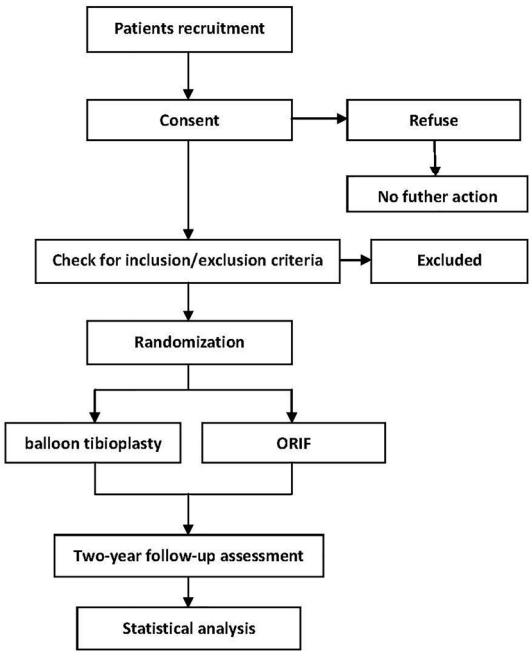
Figure 1. Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.



Flow chart showing the steps in participant recruitment, treatment and analysis. balloon tibioplasty, arthroscopic assisted balloon tibioplasty group; ORIF, open reduction and internal fixation group.

189x170mm (300 x 300 DPI)

supplementary information

title: Arthroscopic-assisted balloon tibioplasty versus open reduction internal fixation (ORIF) for treatment of Schatzker II–IV tibial plateau fractures: Study protocol of a randomized controlled trial

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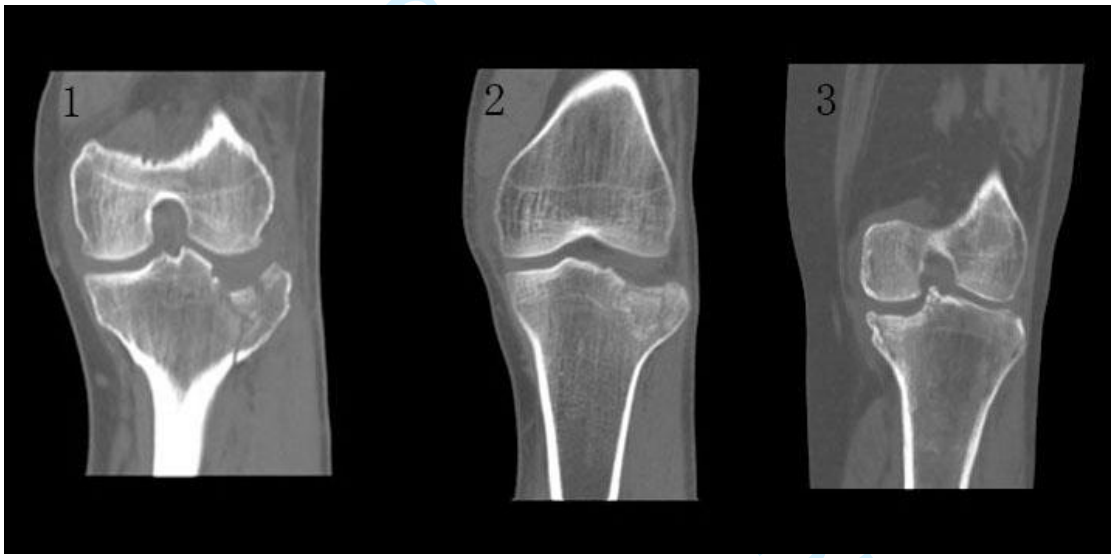
supplementary information, S1

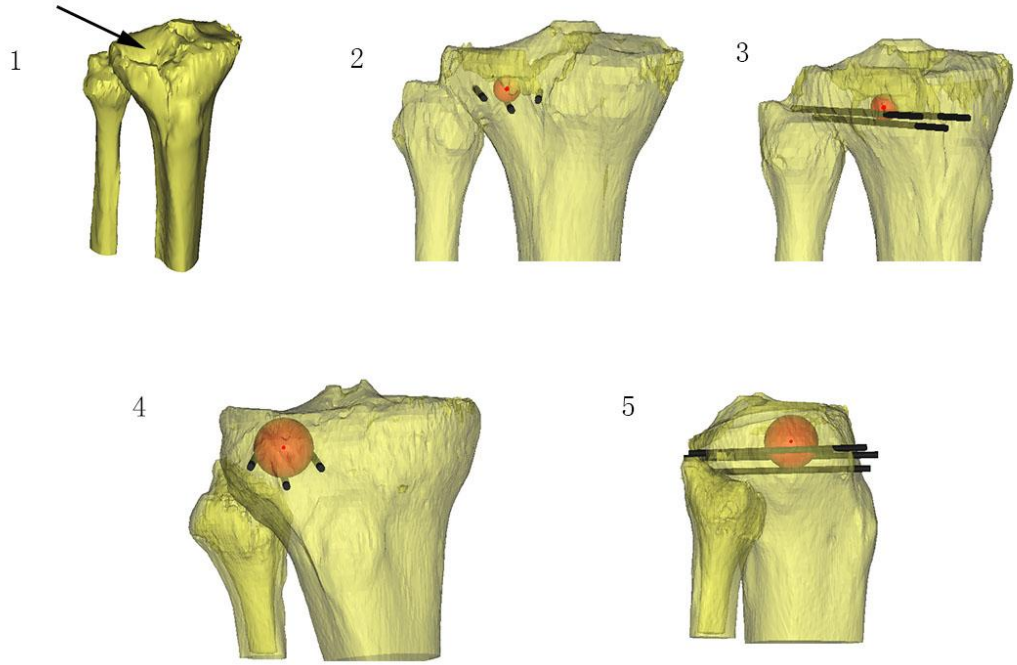
CT scan of Schzatzker II to IV tibial plateau fractures, which conform to our inclusion criteria.



1, CT scan of Schzatzker II tibial plateau fracture, which include the lateral platform split and depression (left limb); 2, CT scan of Schzatzker III tibial plateau fracture, which only include the lateral tibial plateau depression (left limb); 3, CT scan of Schzatzker IV tibial plateau fracture, which only include the medial tibial plateau depression (left limb).

supplementary information, S2

Simulated the operation process of Schzatzker III tibial plateau fracture with Mimics software



1, The black arrowhead in the figure points to the depression of the lateral tibial plateau; 2, Three Kirschner wires and the balloon are placed below the depressed fragment under fluoroscopy (anteroposterior); 3, Three Kirschner wires and balloon are placed below the depressed fragment under fluoroscopy (laterolateral); 4, The balloon slowly inflated with contrast solution, and the depression of the lateral tibial plateau will be anatomical reduction (anteroposterior); 5, The balloon slowly inflated with contrast solution, and the depression of the lateral tibial plateau will be anatomical reduction (laterolateral). After removal of the balloon, calcium phosphate cement will injected into the cavity produced by the balloon under fluoroscopic guidance, ensuring there is no excessive cement overflow into the tibial medullary cavity.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Section/item	Item No	Description
Administrative information		
Title (P1)	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration (P1)	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version (Not mentioned)	3	Date and version identifier
Funding (P7)	4	Sources and types of financial, material, and other support
Roles and responsibilities (P6)	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	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
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale (P2)	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
	6b	Explanation for choice of comparators
Objectives (P6)	7	Specific objectives or hypotheses

Trial design (P2)	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
Methods: Participants, interventions, and outcomes		
Study setting (P2)	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
Eligibility criteria (P3)	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions (P3-P4)	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	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)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes (P4-P5)	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline (P3)	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size (P5)	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment (P5)	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation (P3)	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism (P3)	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation (P3)	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking) (P3)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods (P4)	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management (P5)	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods (P5)	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

Methods: Monitoring

Data monitoring (P5)	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms (P5)	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing (P5)	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

Ethics and dissemination

Research ethics approval (P6)	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments (Not mentioned)	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent (P7)	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality (P5)	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests (P7)	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data (P5)	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care (Not mentioned)	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Dissemination policy (P5)	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
Appendices		
Informed consent materials (Not mentioned)	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens (Not applicable)	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.