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Acute Cuff Tear Repair Trial (ACCURATE): protocol for a multicentre, randomised, placebo-controlled trial on the efficacy of arthroscopic rotator cuff repair

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ABSTRACT

Introduction Rotator cuff tear is a very common and disabling condition that can be related to acute trauma. Rotator cuff tear surgery is a well-established form of treatment in acute rotator cuff tears. Despite its widespread use and almost a gold standard position, the efficacy of an arthroscopic rotator cuff repair is still unknown. The objective of this trial is to investigate the difference in outcome between arthroscopic rotator cuff repair and inspection of the shoulder joint defined as placebo surgery in patients 45–70 years of age with an acute rotator tear related to trauma.

Methods and analysis Acute Cuff Tear Repair Trial (ACCURATE) is a randomised, placebo-controlled, multicentre efficacy trial with sample size of 180 patients. Concealed allocation is done in 1:1 ratio. The randomisation is stratified according to participating hospital, gender and baseline Western Ontario Rotator Cuff Index (WORC). Both groups receive the same standardised postoperative treatment and physiotherapy. The primary outcome measure is the change in WORC score from baseline to 2-year follow-up. Secondary outcome measures include Constant-Murley Score, the Numerical Rating Scale for pain, subjective patient satisfaction and the health-related quality of life instrument 15 dimensions (15D). Patients and outcome assessors are blinded from the allocated intervention. The primary analysis of results will be conducted according to intention-to-treat analysis.

Ethics and dissemination The study protocol for this clinical trial has been approved by the Ethics Committee of the Hospital District of Southwest Finland and Regional Ethics Committee in Linköping Sweden and Regional Committees for Medical and Health Research Ethics South East in Norway. Every recruiting centre will apply local research approvals. The results of this study will be submitted for publication in peer-reviewed journals.

Trial registration number NCT02885714; Pre-results.

Strengths and limitations of this study

- This study will eventually demonstrate the true efficacy of an arthroscopic rotator cuff repair by using a placebo-controlled study design.
- Multicentre setup and three participating countries advance generalisability and external validity of this trial.
- The results of this trial are limited to patients with trauma-related full-thickness supraspinatus tendon tears with acute symptoms.

INTRODUCTION

Background and rationale

The prevalence of full-thickness rotator cuff tears is reported to be between 23% and 32% in previously symptom-free middle-aged patients after having a shoulder trauma.[1–5] An acute cuff tear is associated with impaired quality of life (QoL) and symptoms such as pain in abduction, abduction weakness and night pain.[6] In clinical practice, these patients are often referred to an arthroscopic rotator cuff repair (ACR) for curative treatment.[7] In such an operation, the glenohumeral joint is visualised through arthroscopy, the torn tendon is reattached to its bony footprint, and postoperatively the arm is immobilised in a sling followed by a rehabilitation programme. Good clinical results have been reported on surgical treatment,[4 8–11] and subsequently, the number of operations and cost of treatment have substantially increased during the past years.[12–15] However, these reports cannot be held as a proof that the surgery itself is effective, because of the study designs without a proper control group.

The reported outcome of surgical treatment is thought to be a cumulative effect of three main elements: the critical surgical element, the true placebo effect and non-specific effects.[16 17] The critical surgical element (in this case repairing the torn tendon) is the component of the surgical procedure that is

believed to provide the therapeutic effect and is distinct from aspects of the procedures that are diagnostic or required to access the disease being treated (in this case shoulder arthroscopy).[18] The true placebo effect is not a result of placebo itself but of the context in which placebo is administered, including patient's beliefs, expectations and interaction with the healthcare professionals.[16 19] The non-specific effects are caused by the natural history of the disease, regression to the mean, fluctuations in symptom severity, non-specific effects of taking part in a trial such as patients' reaction to being observed and assessed or to additional contact with clinicians.[20]

A placebo procedure's function is to simulate the active procedure. It has no real therapeutic effect and is by definition inert. Therefore, it is the ultimate comparator for the active treatment in clinical randomised controlled trials. With a placebo as comparator in a controlled setup, both the placebo and non-specific effects are comparable, and the bias is minimised in investigating the true efficacy of an active treatment. There is some evidence that surgery may not be more effective than conservative treatment alone in treating symptomatic degenerative cuff tears.[21] However, this may not be the case with trauma-related tears with acute symptoms. Hitherto there is a lack of evidence, as there are no randomised, placebo-controlled trials on the efficacy of surgical treatment of acute cuff tears.

OBJECTIVES

The objective of the Acute Cuff Tear Repair Trial (ACCURATE) is to investigate the difference in outcome between placebo surgery (PS) and ACR in patients aged 45–70 years with an acute full-thickness supraspinatus tear related to trauma. Our hypothesis is that ACR yields superior results compared with PS in the treatment of an acute tear.

Trial design

ACCURATE is an ongoing randomised, placebo-controlled, multicentre efficacy trial, with two parallel (1:1) treatment arms.

METHODS

Study setting

The study protocol is designed according to Standard Protocol Items: Recommendations for Interventional Trials statement[22] and will be reported using the recommendations in the Consolidated Standards of Reporting Trials statement.[23]

Recruitment

Altogether 14 centres in three countries are signed to recruit patients: eight centres in Finland (Turku University Hospital, Satakunta Central Hospital, Oulu University Hospital, Kuopio University Hospital, Tampere University Hospital, Central Finland Central Hospital, Helsinki University Hospital and Vaasa Central Hospital) and three in both Sweden (Linköping University Hospital, Kalmar County Hospital and Helsingborg Hospital) and Norway (Martina Hansens Hospital, Oslo University Hospital and Sorlandet Hospital HF Kristiansand). All three countries have a country manager who belongs to the ACCURATE study chair. Country managers organise the centre's participating doctors locally.

All eligible patients are asked to participate in the trial, and a written informed consent is obtained. The patients are openly and thoroughly explained the two different treatment modalities at recruitment. Thereafter, the patients are blinded from the treatment modality. The treatment must be commenced within 4 months after the initial traumatic event. All screened patients fulfilling the inclusion criteria are recorded.

Eligibility criteria

The ACCURATE is set out to investigate the performance of ACR under an ideal and controlled circumstance. Therefore, the eligibility criteria are designed in accordance.

Patients with a previously healthy shoulder and acute shoulder pain and dysfunction, following a traumatic event, are referred to trial centres. Involved shoulder surgeons examine and assess the patients for eligibility (aged 45–70 years, acute symptoms after trauma for less than 4 months and MRI documented full thickness supraspinatus tear). A traumatic event is defined as any kind of sudden stretch, pull, fall or impact, on the upper extremity that is associated with the onset of symptoms. Any kind of planned or controlled movement like throwing a ball or lifting an object is not defined as a sudden traumatic event. The traumatic event must happen quickly and without warning, for example, falling down on an outstretched arm or straight on the shoulder, hanging on the arm after falling down. Symptoms have to be typical to cuff tear (pain laterally on the shoulder and/or painful motion arc during abduction or flexion). The patients who fulfil the inclusion criteria are recorded and screened for exclusion criteria.

After a thorough clinical examination, standard shoulder radiographs and MRI are carried out for all potential study patients. Patients with a large rotator cuff tear (sagittal tear size at the level of footprint >3 cm on the MRI), clinical signs of a major tear in infraspinatus or subscapularis (positive clinical rotatory lag sign, external rotation lag sign (ER1 lag) >10°, or lift off lag, involuntary drop against the back) are excluded. Also patients with concomitant injuries (nerve injuries, fractures, bony avulsion of the tendons, dislocated long head of the biceps tendon, humeral head or acromioclavicular joint dislocation) in the shoulder region, which can ultimately interfere with the treatment and interpretation of symptoms, are excluded. The condition of glenohumeral joint, tendons and musculature may also affect the treatment outcome. Therefore, patients with incongruent or osteoarthritic joint, previous symptoms or treatment

of the ipsilateral shoulder, as well as patients with severe fatty degeneration of the muscles of the rotator cuff, are excluded.[24–27]

All inclusion and exclusion criteria are listed in the box 1.

Baseline

All baseline demographics are listed in table 1. High preoperative expectations are described to correlate with better results after rotator cuff surgery[28 29] and low expectations with failure.[30] To address the validity of the trial in the light of expectancies,[31 32] we measure the preoperative expectations with Stanford Expectations of Treatment Scale.[33] Depression and anxiety may have a negative impact on self-assessed outcome measurements in patients scheduled for rotator cuff repair.[34] Therefore, we assess the preoperative psychological distress with the Hospital Anxiety and Depression Scale.[35]

Enrolled patients must be scheduled for intervention within 4 months from the initial trauma. Preoperative scoring is arranged within 2 weeks before surgery.

Interventions

All patients receive regional nerve block and/or general anaesthesia. Also prophylactic antibiotic is administered for all patients. These are not standardised but delivered as a routine practice of each hospital. The arthroscope is introduced in the glenohumeral joint, and thereafter a thorough diagnostic arthroscopy is performed, and a global assessment of the joint surfaces is performed according to the Outerbridge classification.[36] The presence of a full-thickness cuff tear is verified by introducing a probe/switching stick through the subacromial space into the joint. If the diagnostic arthroscopy reveals a partial thickness cuff tear only, a total width of infraspinatus or subscapularis tear or a fully dislocated long head of the biceps tendon with concomitant subscapularis tear, the patient is excluded from the trial and treated according to local routine. After the diagnostic arthroscopy and confirmation of the eligibility criteria, the patient is randomly assigned to ACR or PS and treated accordingly. A detailed list of findings to be documented during the diagnostic arthroscopy is given in table 2.

Study interventions

Rotator cuff repair

A biceps tenotomy or tenodesis may be performed according to surgeon preference if the biceps tendon is noted to be frayed, unstable or inflamed. An additional acromioplasty may be performed according to surgeon preference if there are signs of mechanical tightness (fraying on the undersurface and close contact to the cuff structures). The rotator cuff insertion is prepared, and the cuff tear is repaired to its anatomic location using suture anchors according to surgeon preference. Although an eligible patient should have an anatomically repairable tear, there is always a chance that in vivo the torn tendon is not completely repairable on its anatomic insertion.

Box 1 Inclusion and exclusion criteria

Criteria for Inclusion

1. Age of patient is over 45 years and below 70 years at the time of injury.
2. Acute onset of shoulder symptoms after a traumatic event (any kind of sudden stretch, pull, fall or impact, on the shoulder that is associated with the onset of symptoms).
3. Shoulder symptoms relating to rotator cuff tear=pain laterally on the shoulder and/or painful motion arc during abduction or flexion.
4. MRI documented full-thickness supraspinatus (ssp) tear.

Criteria for exclusion

1. Traumatic event of the shoulder due to a criminal act of violence with legal consequences.
2. A delay of more than 4 months after the onset of symptoms of trauma to the day of intervention.
3. Arthroscopically documented partial thickness rotator cuff tear only.
4. A large MRI documented full-thickness rotator cuff tear, sagittal tear size at the level of footprint larger than 3 cm.
5. MRI or arthroscopically documented total width of infraspinatus or subscapularis tear.
6. MRI or arthroscopically documented fully dislocated biceps tendon (biceps out of the groove) with concomitant subscapularis tear.
7. Positive clinical rotatory lag sign (ER1 lag (>10°), lift off lag (involuntary drop against the back) and horn blower lag (involuntary internal rotation of the forearm in supported elevated position).
8. Marked fatty degeneration in any of the cuff muscles (more than Fuchs/Goutallier grade 2[27]).
9. Radiographically or MRI-documented concomitant fracture line of the involved extremity or bony avulsion of the torn tendon or dislocation of the humeral head or the acromioclavicular joint.
10. Concomitant clinically detectable motor nerve injury affecting the shoulder.
11. Radiographically documented severe osteoarthritis of the glenohumeral joint, Samilson-Prieto 2 or above.
12. Non-congruency of the glenohumeral joint in radiographs (Hamada stage 2 or above).
13. Clinical stiffness of the glenohumeral joint (severely limited passive range of motion: glenohumeral external rotation <30°, and abduction with stabilised scapula <60°).
14. Previous surgery of the affected shoulder (affecting clavicle, scapula or upper third of the humerus).
15. Earlier sonographic or MRI finding of a rotator cuff tear.
16. Previous symptoms of the ipsilateral shoulder requiring conservative treatment (glucocorticosteroid injections and/or physiotherapy) delivered by healthcare professionals during the last 5 years.
17. Systemic glucocorticosteroid or antimetabolite medication during the last 5 years.
18. Ongoing treatment for malignancy.
19. American Socety of Anesthesiologist (ASA) classification 3 or 4.
20. Patient's inability to understand written and spoken Finnish, Norwegian or Swedish.
21. History of alcoholism, drug abuse, psychological or other emotional problems likely to jeopardise informed consent.
22. Patients with a contraindication/non-compliance for MRI examination or use of electrocautery devices.
23. Previous randomisation of the contralateral shoulder into the Acute Cuff Tear Repair Trial.
24. Patient's denial for operative treatment and/or participation in the trial.

Table 1 Baseline demographics

	Rotator cuff repair	Placebo surgery
Age (years), mean (SD)		
Gender (female/male), n (%)		
Dominant side affected, n (%)		
Previous symptoms, n (%)		
No pain ever		
Pain in shoulder at any point of time		
Pain during the past year		
Smoking habits, n (%)		
Smoking		
Non-smoking		
Occupation		
Mechanism of injury, n (%)		
Stretch		
Pull		
Fall		
Impact		
Energy of injury, n (%)		
<Fall from own height		
>Fall from own height		
Duration of symptoms (days/weeks from the trauma to the operation), mean (SD)		
Working status, n (%)		
Student		
Unemployed		
Retired		
On sick leave		
Disability pension		
Working		
Treatments after the trauma, n (%)		
Injections		
Physiotherapy		
Pain killers		
Outcome measures		
Pain NRS (0–10) at night, mean (SD)		
Pain NRS (0–10) at rest, mean (SD)		
Pain NRS (0–10) during activity, mean (SD)		
WORC (WORC %-index 0%–100%)		
Physical symptoms, mean (SD)		
Sports/recreation, mean (SD)		
Work, mean (SD)		
Lifetime, mean (SD)		
Emotions, mean (SD)		
Total %-index, mean (SD)		
Constant-Murley Score, mean (SD)		
Pain		
Activities of daily living		
Range of motion		
Shoulder power		
Total score		
15D		
Stanford Expectations of Treatment Scale		
Hospital Anxiety and Depression Scale		

NRS, Numerical Rating Scale; WORC, Western Ontario Rotator Cuff Index; 15D, 15 dimensions.

In this unlikely circumstance, a partial reconstruction is carried out according to surgeon preference. The retraction of the tear will be measured and documented on the MRI images. No additional procedures are performed with regard to possible concomitant pathologies of articular cartilage or labrum. The wounds are closed, and the arm is placed in a sling. A detailed list of procedures to be documented in the rotator cuff repair group is given in box 2.

Placebo surgery

Only the joint space is evaluated; no subacromial scoping is performed. Nothing is to be removed or excised, and the use of any electrocautery or shaver device is not allowed. Altogether 3 –5 small skin stab incisions are made in typical locations resembling locations of typical rotator cuff repair. After the evaluation, the wounds are closed, and the arm is placed in a sling. The time spent in the operating theatre with patients in the placebo

Table 2 Pathology during the diagnostic arthroscopy

	Rotator cuff repair	Placebo surgery
Condition of humerus articular surfaces, n (%)		
Outerbridge grade 0		
Outerbridge grade 1		
Outerbridge grade 2		
Outerbridge grade 3		
Condition of glenoid articular surfaces		
Outerbridge grade 0		
Outerbridge grade 1		
Outerbridge grade 2		
Outerbridge grade 3		
Condition of the biceps tendon, n (%)		
Normal		
Tendinosis		
Subluxation		

Box 2 Procedures in the rotator cuff repair group

Anatomic reconstruction, n (%).
Partial reconstruction, n (%).
Brand of suture anchors.
Number of suture anchors, (%)
  1.
  2.
  3.
  4.
Biceps procedure, n (%)
  None.
  Tenotomy.
  Tenodesis.
Acromioplasty, n (%)
  Yes.
  No.

group should resemble the time spent with patients in the active treatment group and hence give an impression of a rotator cuff repair.

Postoperative physiotherapy

The postoperative care and rehabilitation is identical in both the ACR and PS groups. The rehabilitation programme is based on the current literature[37–42] as well as clinical experience. The programme consists of one initial phase (0–4 weeks) were the patients are immobilised in a sling, and during this time, the exercise programme is standardised. After the sling has been phased out, the rehabilitation programme consists of three phases. Phase 1 consists of active assisted range of motion exercises, phase 2 consists of active unloaded exercises and phase 3 consists of dynamic strengthening exercises. There are several exercises to choose from in each phase in purpose to fit each patients shoulder disability. The physiotherapist decides when the patient is ready to move on to the next phase, considering aspects of quality of motion and pain, in accordance with restrictions. The patients will have approximately 15 visits of physiotherapist-guided exercises sessions during a 5-month period. Each visit will take approximately 30–45 min. In between these guided exercise sessions, patients will perform home exercises according to the different phases. An exercise diary is used to encourage adherence and is handed out at the first visit.

A detailed exercise programme is presented in online supplementary appendix 1. All patients receive a prescription for analgetics according to local routine to be used if needed. The patients receive a sick leave up to 12 weeks, which can be extended if needed.

Outcomes

Primary outcome

Western Ontario Rotator Cuff Index (WORC)

The primary outcome measure is the change in WORC[43] at 2-year follow-up compared with baseline. WORC is a disease specific self-reported instrument for rotator cuff disease. It consists 21 visual analogue scale (VAS) items in five domains: physical symptoms (six items), sports/recreation (four items), work (four items), lifestyle (four items) and emotions (three items). All items respect QoL aspects that can particularly be influenced by rotator cuff injury. Each item has a possible score from 0 to 100 (100 mm VAS), and these scores are added to give a total score from 0 to 2100. A score of 0 implies no reduction in QoL, and a score of 2100 is the worst score possible. The data can be converted to a percent score by inverting the raw score and then converting it to a score out of 100 (2100 – 'patient WORC raw score'/21). The domains are based on the WHO definition of health. WORC is determined to have the highest ratings among all shoulder instruments.[44] The minimally clinically important change (MCIC) for WORC is reported to be 275 points or 12.8%.[45]

Secondary outcomes

Constant-Murley Score

The Constant-Murley Score[46] is the most widely used shoulder evaluating instrument in Europe despite its limitations.[47–49] The 100-point scoring scale takes into account both subjective and objective measurements and is divided into four domains (pain: 15 points; activities of daily living: 20 points; range of motion: 40 points; strength: 25 points). Minimal clinically important difference (MCID) for Constant-Murley Score is reported to be between 10.4 and 17 points.[50 51]

Numerical Rating Scale for pain (Pain NRS)

Pain NRS is a unidimensional measure of pain intensity.[52] The 11-point numeric scale ranges from '0' representing no pain to '10' representing pain as bad as you can imagine or worst pain imaginable. We use Pain NRS to measure patient's perceived pain intensity during activity, at rest and at sleep during the last week preceding the assessment. MCIC for pain NRS is reported to be 2 points or 30%.[53 54]

15D

The 15 dimensions (15D) is a generic, comprehensive (15-dimensional), self-administered instrument for measuring health-related quality of life.[55] It combines the advantages of a profile and a preference-based, single index measure. A set of utility or preference weights is used to generate the 15D score (single index number) on a 0–1 scale. The estimated MCIC in the 15D scores is reported to be 0.015.[56]

Subjective patient satisfaction

To assess the patient's global satisfaction with the treatment outcome we use a 5-point Likert scale for evaluation.

Imaging studies

Preoperative imaging studies include standard shoulder radiographs and MRI. Radiographs and MRI studies will be done for both groups at 2-year, 5-year and 10-year follow-ups to assess any signs of osteoarthritis (according to Samilson and Prieto) or cuff tear arthropathy (according

to Hamada classification) in the radiographs and muscle fatty degeneration (according to Fuchs/Goutallier) and tear progression or re-tears (according to Sugaya[57]) in the MRI. Detailed list of parameters to be reported from the imaging studies are in table 3.

Participant timeline

Detailed schedule for the assessments are presented in the table 4 and the flow chart of the trial is shown in figure 1.

Assignment of intervention

Allocation

We use computerised internet-based online randomisation software application (https://www.randomize.net/) to allocate patients to the intervention (rotator cuff repair) or control (PS) group. Randomisation is done in the operation theatre after the diagnostic arthroscopy when the final confirmation of the eligibility criteria is ascertained. The randomisation is stratified, according to participating hospital (X), gender (2), and baseline WORC index (three separate lists: <20%, 20%–40% and >40%), into (Xx2×3) 6X randomisation lists, respectively (with variable block size known only by the trial statistician).

Blinding

The patients are openly explained the different treatment modalities at recruitment. Thereafter, the patients, the hospital staff and outcome assessors are unaware of treatment allocation. Only the operating doctor and involved operating theatre personnel know the treatment group of the patient and are not allowed to share this information further. The operating doctor will not see the patient after the operation at any point. There will be no information on the treatment group in the patient files or hospital charts. The content of patient operative file includes information on the date, doctor, randomisation number and text (arthroscopy of the right/left shoulder and treatment according to ACCURATE protocol). Registered code of the intervention in the official hospital charts will be the code for ACR. Patient follow-ups are performed by a blinded physiotherapist. Whenever needed, a blinded doctor is consulted. There is a blinded doctor who will see the patient at the outpatient clinic at 3 months postoperative, which is the normal routine in our hospitals.

The blinding may only be unrevealed in case of serious adverse event (AE), treatment failure (serious persisting symptoms 6 months after the treatment) or discontinuation. The need of unblinding is evaluated by the blinded doctor, who then contacts the trial country manager who decides on the unblinding. In no case must the local operating doctor and the blinded doctor discuss directly with regard to issues within this trial.

Table 3 Imaging studies parameters at baseline and at follow-up

	Rotator cuff repair	Placebo surgery
Shoulder radiograph		
Osteoarthritic changes, n (%)		
Samilson and Prieto grade 1		
Samilson and Prieto grade 2		
Samilson and Prieto grade 3		
Cuff tear arthropathy, n (%)		
Hamada grade 1		
Hamada grade 2		
Hamada grade 3		
Hamada grade 4		
Hamada grade 5		
Shoulder MRI, n (%)		
Arthrography MRI		
Native MRI		
Supraspinatus		
Retear if operated, n (%)		
Sugaya type I		
Sugaya type II		
Sugaya type III		
Sugaya type IV		
Sugaya type V		
Sagittal tear size (mm), mean (SD)		
Coronal tear size (mm), mean (SD)		
Fatty degeneration, n (%)		
Fuchs/Goutallier grade 0		
Fuchs/Goutallier grade 1		
Fuchs/Goutallier grade 2		
Fuchs/Goutallier grade 3		
Fuchs/Goutallier grade 4		
Warner tangent sign, n (%)		
Positive		
Negative		
Muscle oedema, n (%)		
Yes		
No		
Infraspinatus		
Retear if operated, n (%)		
Sugaya type I		
Sugaya type II		
Sugaya type III		
Sugaya type IV		
Sugaya type V		
Sagittal tear size (mm), mean (SD)		
Coronal tear size (mm), mean (SD)		
Fatty degeneration, n (%)		
Fuchs/Goutallier grade 0		

Continued

Table 3 Continued

	Rotator cuff repair	Placebo surgery
Fuchs/Goutallier grade 1		
Fuchs/Goutallier grade 2		
Fuchs/Goutallier grade 3		
Fuchs/Goutallier grade 4		
Muscle oedema, n (%)		
Yes		
No		
Subscapularis		
Retear if operated, n (%)		
Sugaya type I		
Sugaya type II		
Sugaya type III		
Sugaya type IV		
Sugaya type V		
Sagittal tear size (mm), mean (SD)		
Coronal tear size (mm), mean (SD)		
Fatty degeneration, n (%)		
Fuchs/Goutallier grade 0		
Fuchs/Goutallier grade 1		
Fuchs/Goutallier grade 2		
Fuchs/Goutallier grade 3		
Fuchs/Goutallier grade 4		
Muscle oedema		
Yes		
No		
Teres minor		
Fatty degeneration, n (%)		
Fuchs/Goutallier grade 0		
Fuchs/Goutallier grade 1		
Fuchs/Goutallier grade 2		
Fuchs/Goutallier grade 3		
Fuchs/Goutallier grade 4		
Muscle oedema, n (%)		
Yes		
No		
Long head of the biceps tendon, n (SD)		
Normal		
Subluxation		
Frayed		
Ruptured		
Tendon missing		
Tenodesis		

Failure to maintain blinding can lead to differences in perceived treatment and can contribute to differences between the active treatment and placebo groups. This can limit the internal validity of the trial.[31]

We use a 5-point Likert scale blinding index to evaluate the success and maintaining of blinding at discharge, 3 months, 6 months, 1 year and 2 years after the intervention.[58]

Declined cohort

The patients who are otherwise eligible but do not want any operation and/or do not want to participate are asked for a permission for a later patient file follow-up and to participate in a follow-up study. An informed consent is obtained from these patients. The patient receives the treatment he or she desires after counselling with the involved doctor. The baseline demographics together with treatment modality and WORC outcome measure at baseline, 1 and 2 year follow-up are collected (table 1).

Patient and public involvement

Patients were not involved in the design, recruitment or conduct of this study. Patients will be informed by the results of the study after completion.

DATA MANAGEMENT AND ANALYSIS

Data management

All data for this study is collected from trial specific patient report forms. The patient information is also stored electronically. The original paper forms with regard to patient evaluation are stored securely by the local operating doctor, blinded doctor and the physiotherapist in a locked folder. The original paper forms of screened, recruited and treated patients are stored securely by the local operating doctor. All imaging data are stored in individual CD-R discs and sent by mail to the study nurse after completion of the recruitment and at 2-year, 5-year and 10-year follow-up.

All data are stored and secured in a specific paper form and electronic study subject register held at the coordinating centre: Turku University Hospital, TULES Division, Upper Extremity Department. Informed consent is collected, regarding transformation of data to Finland, from Sweden and Norway. The trial patient data are stored for 10 years after the final follow-up.

Sample size

The power calculation is based on assumed behaviour of the WORC score. The mean score value at baseline is assumed to be 40%.[45 57] The mean score of the best treatment group after the follow-up is assumed to be 85%.[58] The SD is assumed to be 18%.[57] The trial is set out to reliably detect the reported minimally clinically important change of WORC, that is, 273 points (13% of the total 2100 points).[45] Therefore, the score of the most inefficient treatment group is assumed to be less than 73%. The correlation between measurements during the follow-up is estimated to be about 0.40–0.50. In an analysis of variance test with alpha of 0.05 and power of 95%, we can expect the findings to be statistically significant if the number of subjects in each group is 72. Because of

Table 4 Schedule for the assessments

Assessment	Screening	Baseline	Intervention (within 4 months after trauma)	3 months	6 months	1 year	2 years	5 years	10 years
Screening form	X								
Radiograps and MRI	X						X	X	X
Clinical examination		X		X (BD+PT)	X (PT)	X (PT)	X (PT)	X (PT)	X (PT)
Preoperative data form		X							
Randomisation		X							
Intraoperative data form		X							
Blinding index			X*	X	X	X	X		
SETS	X								
HADS	X			X	X	X	X	X	X
Pain NRS	X			X	X	X	X	X	X
15D	X			X	X	X	X	X	X
CM score	X			X	X	X	X	X	X
WORC	X			X	X	X	X	X	X
Working status	X			X	X	X	X	X	X
Analgesic usage	X			X	X	X	X	X	X
Supplementary treatment	X			X	X	X	X	X	X
Subjective satisfaction				X	X	X	X	X	X
Amount of supervised PT visits									
Exercise diary					X				
Question on treatment satisfaction†						X	X	X	X
Adverse event form‡			(X)	(X)	(X)	(X)	(X)	(X)	(X)
Discontinuation form‡				(X)	(X)	(X)	(X)	(X)	(X)
Unblinding form‡					(X)	(X)	(X)	(X)	(X)
Reoperation form‡				(X)	(X)	(X)	(X)	(X)	(X)

*After the intervention, at the point of discharge.
†Looking back at your shoulder trauma and the treatment that you initially received, would you choose to undergo the same treatment if you could turn back time?
‡If required.
BD, blinded doctor; CM Score, Constant-Murley Score; HADS, Hospital Anxiety and Depression Scale; Pain NRS, Numerical Rating Scale for pain; PT, physiotherapist; SETS, Stanford Expectations of Treatment Scale; WORC, Western Ontario Rotator Cuff Index; 15D, 15 dimensions.

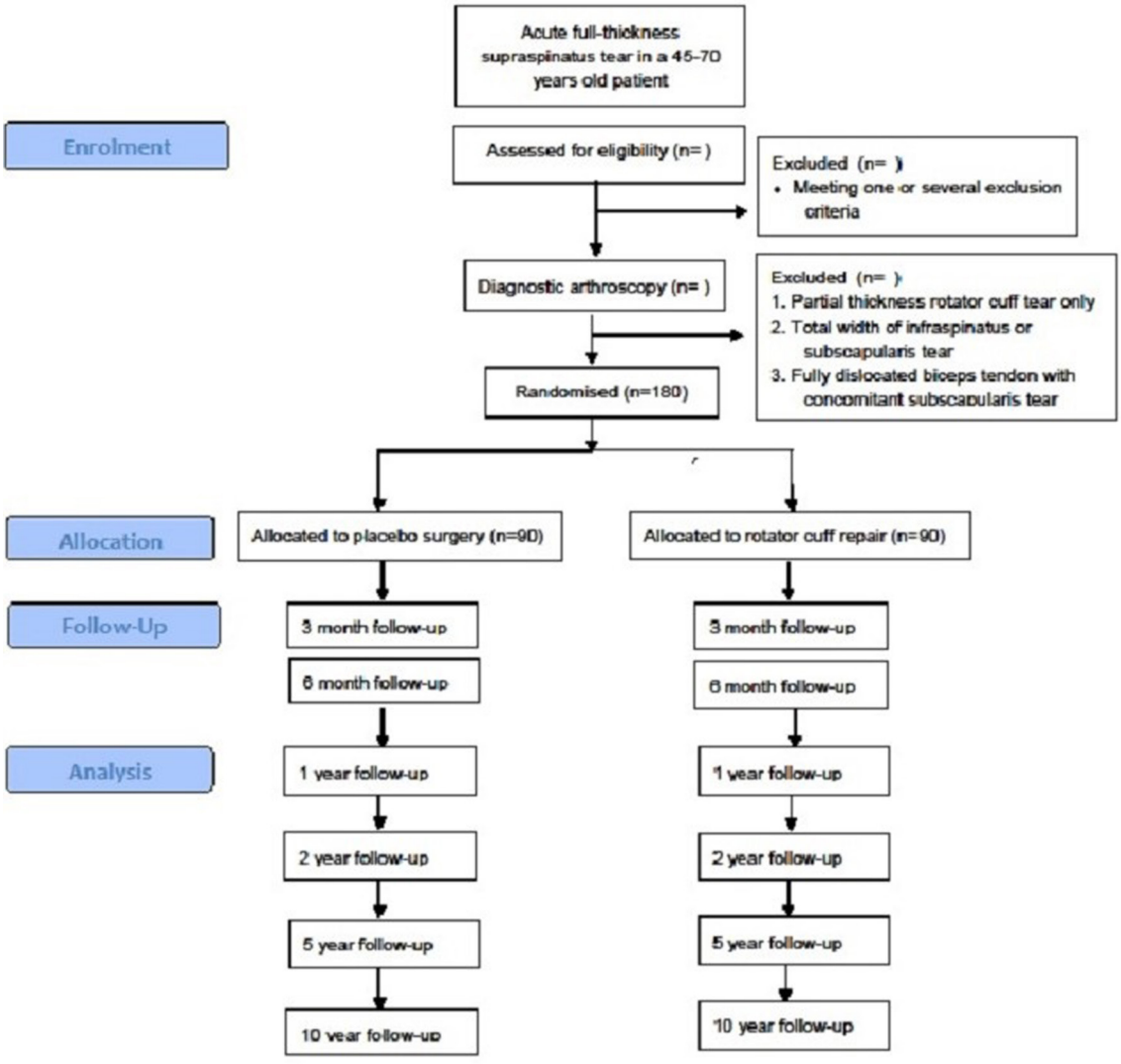

Figure 1 Flow chart of the trial.

possible drop-outs, the minimum number of subjects per group is decided to be 90.

Missing items

Items of WORC score subdomains are summed to form a score for each subdomain, and subsequently total WORC score is a sum of all subdomain scores. Due the nature of WORC score and summing of items, missing items would affect the score interpreting 'worst case scenario'. Therefore, actions for missing items are applied.

Substituting average value

Missing individual items in WORC score subdomains are considered as missing at random if only one item is missing per subdomain and thus substituted with average value of available item in each subdomain. Substitution is justified due to reasonably high correlation between items within subdomains.[59]

Last observation carried forward

If WORC score is missing for any subdomain on adjacent follow-up measures, the last available measurement is substituted.

Hot deck imputation

Missing WORC scores on any follow-up measurement are substituted using 'Hot deck' method by matching patients to each other using demographic information such as age, centre, gender and WORC score at baseline and substitute missing value with matched patients WORC score on at the follow-up.

Loss to follow-up

Because of possible drop-outs, the minimum number of subjects per group is decided to be 90. This allows retaining statistical power with losses to follow-up. Imputations methods will be applied to primary outcome on follow-up measures unless the follow-up record was missing completely, for example, dropout of a subject.

Retention

The study nurse stores and holds the paper and electronic patient registry for this trial and checks the data for uncompleted items. In case of non-adherence the investigating doctor is contacted and the reason for non-adherence is collected.

Statistical methods

After completion of 1-year, 2-year, 5-year and 10-year follow-up, the cohort data are collected by the principal investigator and will be analysed by an independent statistician (blinded from the treatment arms). Methods suitable for clinical trial regarding comparison of parallel treatment groups with repeated measurements.

A detailed statistical analysis plan (SAP) will be prepared prior to database lock. Any deviations to the planned analyses specified within the SAP will be justified in writing and presented within the final study report.

The intention-to-treat (ITT) dataset will include all enrolled patients who received study treatment and have at least one post baseline primary outcome measurement available. The per-protocol (PP) dataset is a subset of the ITT dataset excluding patients or measurements for a given patient with major protocol violation(s) expected to alter the outcome to treatment. The primary outcome measures will be analysed using both the ITT (primary analysis) and the PP dataset.

All background, outcome and safety variables will be summarised by visits. In addition to absolute values, changes relative to baseline values will be summarised, if feasible. Correlations among the study variables may be investigated. The results of outcome variables over the course of the study will be summarised descriptively. Disposition and reasons for discontinuation will be summarised for all patients together with treatment exposure and study duration by treatment group.

The analysis of the primary outcome measure will be done using the generalised linear mixed models. Generalised autoregressive covariance structure will be used to take into account spatial differences between measuring timepoints. Definition and usage of factors and covariates and the full model is described in more detail in SAP. All results will be presented with 95% CIs. A two-sided significance level of 0.05 will be used. Multiple correction is applied to all pairwise comparisons including timepoint comparisons and is presented with unadjusted p values and CIs.

The analysis of secondary outcome measures (change in Constant-Murley Score compared with baseline at 2 years; change in patients' shoulder pain during the last week at rest, during activity and at night [continuous]; change in subjective pain intensity measure [continuous pain NRS]; change in generic health-related QoL instrument 15D [continuous]; subjective patient satisfaction [classifying]; and radiographic findings) will be analysed with the same approach as the primary outcome when appropriate and otherwise statistical methods for repeated measures or methods for paired data (eg, McNemar's test for binary data, Wilcoxon signed-rank test for ordinal data and paired t-test for continuous data). Subjects attaining change in WORC and Constant-Murley Score greater than MCID are considered as *responders* to the treatment. Evaluation of reaching MCID is done in each timepoint individually, and responder status is carried over to all adjacent timepoints once attained. Responder analysis will be carried out with generalised logistic regression model with responder/non-responder as an outcome. In addition, generalised linear mixed models may be used to further characterise the results. All secondary analyses are designed to be supportive of the analysis of the primary endpoint, and each analysis will be undertaken at the two-sided 5% level of significance.

If feasible, subgroup analyses will be conducted, for example, by (pooled) centre, age, gender, handedness, tear size and appearance, mechanism of injury and smoking habits.

Statistical analysis, tables and patient data listings will be performed with SAS V.9.3 for Windows.

Blinded data interpretation

To minimise the chance of misleading interpretation of the final data, we use the recommended approach of blinded data interpretation.[60] Breaking of treatment code is done on reported statistical results, not on the data itself before analysis. The approach involves developing two interpretations of the results on the basis of a blinded review of the primary outcome data (treatment A compared with treatment B). One interpretation assumes that A is the rotator cuff repair group and another assumes that A is the PS group. After agreeing on the interpretations, the investigators record their decisions and sign the resulting document. The randomisation code is then broken, the correct interpretation chosen and the manuscript finalised.

Monitoring

Data monitoring

The patient data are monitored weekly by the research nurse. In case of delay/interruption in patient data, the study nurse informs the local doctor, physiotherapist and the principal investigator in Finland.

The trial leader performs an interim analysis of the available outcome data when 90 (50%) patients have been recruited and treated to confirm safety and ethical considerations of the study. In case of significantly more AEs or reoperations within any of the treatment modalities, a premature discontinuation of the study is considered.

Harms

AEs are documented at the scheduled and unscheduled clinical visits. The patients are urged to report any AEs or health-related issues immediately after appearance to the blinded doctor. In case of any AE, the blinded doctor informs the study nurse and the principal investigator in Finland. All AEs regardless of suspected relationship to the study will be recorded. The blinded doctor assesses

the likelihood of the AE to be caused by the study treatment on a six-grade causality scale (none, unlikely, possible, probable, definite and cannot be classified). The severity of all AEs is assessed on a three-grade scale (mild, moderate and severe). All AEs are dealt with in a symptomatically adequate manner, and the patients are hospitalised if needed.

ETHICS AND DISSEMINATION

Ethical approval

Every recruiting centre will apply local research approvals. ACCURATE will be conducted according to the World Medical Association Declaration of Helsinki. The template informed consent (in Finnish, Swedish, Norwegian and English) is contained in online supplementary appendix 2.

Protocol amendments

Any modifications to the protocol that may affect the conduct of the study, the potential benefit of the patient or patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects, will require a formal amendment to the protocol. Such amendment will be agreed on by ACCURATE study chair (main authors of this protocol) and will need approval by the ethics committees prior to implementation.

Administrative changes of the protocol are minor corrections and/or clarifications that have no effect on the way the study is to be conducted. These administrative changes will be agreed on by ACCURATE study chair and will be documented and updated in the trial registry at ClinicalTrials.gov.

Consent or assent

Informed consent will be obtained by the local recruiting doctor in each participating centre. The consent form is either in Finnish, Swedish or Norwegian. Consent is also obtained from the eligible patient who do not want to participate in the study.

Confidentiality

All patient data (paper forms and electronic database) is handled with confidentiality and will be stored securely. During analyses the patient's personal identification numbers are blinded.

Access to data

The study nurse holds the register of treatment groups and patients within the trial. Only the study nurse may access the patient data during the data collection. During the interim analyses, the trial leader has access to the data set. At follow-ups, the gathered patient data are analysed by the statistician and authors of the manuscript. The treatment arms will be uncoded after the blinded data interpretation, and the study nurse is the only one who knows the codes.

Ancillary and post-trial care

All patients enrolled in the trial have the possibility to contact the local blinded doctor with regard to their treated shoulder at any stage during the trial. A patient may also withdraw consent and discontinue the study prematurely at any time if he or she so wishes. The patients are informed of the trial results by letter after the analyses of 2 years follow-up is completed.

Dissemination policy

The results of this study will be submitted for publication in peer-reviewed journals.

DISCUSSION

In this ACCURATE protocol, we describe the design of a placebo-controlled randomised trial on the efficacy of ACR versus PS in patients with full-thickness supraspinatus tear related to trauma with acute symptoms. This enables evaluation of clinical benefit of ACR for the patient, using a validated patient-reported outcome measure. To our knowledge, this is the first placebo-controlled trial on the subject. The rationale for the ACCURATE trial includes: (1) rising incidence of ACRs worldwide; (2) almost a gold standard position of rotator cuff repair on trauma-related cuff tears with acute symptoms; and (3) the lack of evidence on the efficacy of ACR.

There are several patient-related factors that may influence the outcome of cuff tear in light of cuff integrity, shoulder function and patient satisfaction, such as tear size, number of involved tendons and fatty infiltration of the rotator cuff musculature.[61] In the ACCURATE, these factors are controlled by precise exclusion criteria. The internal validity of the trial is further ensured by: minimising bias by use off an online computer-based randomising system, blinding of patients and outcome accessors, use of appropriate statistical testing, blinded data interpretation and an adequate sample size based on a power calculation. In addition to the patient-related factors, the repair technique of the tear can influence the final outcome and retear rates according to reports of patient series.[62 63] However, the latest meta-analyses showed no sound evidence on the difference in clinical outcome or retear rates between single and double row repair in small to medium sized (<3 cm) tears.[64–67] Therefore, we left the decision of repair technique to the operating surgeon.

A cuff tear most often involves the supraspinatus tendon,[2] and therefore an eligible patient (without concomitant pathologies) in the ACCURATE is an ideal candidate for ACR according to current clinical practice. The results of this trial are generalisable to patients with trauma-related tears of the superior part of the rotator cuff with acute symptoms and applicable in evaluating the treatment paradigm. The multicentre setup and three participating countries further advance generalisability and external validity of the trial.

A major challenge in the ACCURATE, like in many placebo-controlled surgical trials, is to recruit a required number of patients in a reasonable period of time.[17] ACCURATE tries to tackle this obstacle by a large number of participating centres and by regular bulletins. Some problems can certainly arise from a large number of recruiting doctors. Potential lack of equipoise, which might reflect on the doctors' presentation when counselling and recruiting the potential study patient. From the patient's side, for example, previous positive experiences from surgery or a strong preference for either operative or conservative treatment by the patient, family member or some other doctor. These barriers are dealt with in regular meetings and correspondence with guidance to thorough explanation and wording when recruiting potential participants.

The use of placebo may be criticised for leaving half of the patients not repaired. The ethical considerations regarding the trial setup are presented in box 3 according to Savulescu *et al*.[20] The main clinical concern is the potential tear progression and further fatty degeneration of the rotator cuff muscles, as reported in a purely degenerative setting.[68–70] However, a retear or persistent defect in the rotator cuff, after repair of small-sized to medium-sized tears, is a common finding in up to 10.6%–50% of the patients.[71–73]

Interestingly, the results of a meta-analysis by Russell *et al*[74] suggest that the clinical outcome is similar after the rotator cuff repair regardless of the structural integrity of the repair. A cuff tear may also be associated with global degeneration of the glenohumeral joint. By following these patients 10 years after injury, the effect of ACR on the eventual development of ostearthritis and/or cuff tear arthropathy may be detected. There are only a few studies available on the evolution of a non-operatively treated traumatic tendon tears, and there is, to date, no randomised trial with published results.[1 69 75] Accordingly, significant short-term tear size progression is unlikely. The potential progression is evaluated with a control MRI follow-up. Moreover, the clinical presentation of trial participants is regularly monitored for any complaint/AE, and the patients may be unblinded if necessary.

It can be estimated that in average 20% of people in their 40–70s have an asymptomatic full-thickness cuff tear, and the prevalence increases with age.[76] Due to high number of asymptomatic degenerative tears, the definition of a traumatic or acute cuff tear is controversial. It is thought that a significant trauma can rupture a healthy rotator cuff tendon. However, the tendons are usually weakened by increasing age-related degeneration.[77] Attempts have been made to distinguish between acute and chronic degenerative tears, through MRI or ultrasound imaging,[78–80] without any accepted consensus. We argue that the criteria for an acute cuff tear, introduced in the ACCURATE protocol, reflect the general practice. There is a possibility that an MRI documented cuff tear after a trauma is actually an acute-on-chronic tear with acute symptoms. However, these tears cannot be

Box 3 Ethical considerations about the trial setup

Criteria to make surgical placebo-controlled trial ethical outlined by Savulescu *et al*.

The presence of equipoise

There are no randomised controlled trials on acute rotator cuff tears; that is, there is a lack of unbiased evidence for efficacy of the arthroscopic rotator cuff repair. There is a meta-analysis[21] from three randomised controlled trials on the treatment of mainly non-traumatic rotator cuff tears, and it showed clinically similar results between operative and conservative treatment.

Preliminary evidence for efficacy of the procedure

There are several open-label studies[4 8–11] on the operative treatment of rotator cuff tears. The results usually range from good to excellent and in terms of outcome measures the overall improvement has been clinically significant. These studies, however, are highly biased because of the study design itself; not controlling the critical surgical element, true placebo effect and non-specific effects.[16 17] In surgical treatment of rotator cuff tear the outcome is always a subjective change in quality of life because of non-life-threatening nature of the condition. The critical element is the repair/suturing the torn tendon. The aim is to relieve pain and improve function by reinserting tendon with suture anchors back into its footprint where it should biologically heal. However, considerable amount of these sutured tendons do not heal or they rerupture. Furthermore, a retear do not seem to affect the outcome[74]; patients with a retear are as satisfied as patients with an intact tendon. Taking into account the previously mentioned facts, there exists a doubt whether the improvement seen in the open-label studies is caused by the rotator cuff repair or not.

Minimising risk for patients in the placebo arm

In the ACCURATE, the placebo arm includes a diagnostic arthroscopy and supervised physiotherapy. The potential risks for patients are associated with operative treatment and include: preoperative medication (usually pain killers and sedatives/anksiolytes), plexus anaesthesia, global/total intravenous anaesthesia, prophylactic antibiotic, diagnostic arthroscopy itself and postoperative medications (mainly pain killers). All medications can cause side effects, but this risk is estimated to be low. Surgery, which is by definition invasive, comes always with a risk of adverse events or complications. A complication is defined as an event or condition that requires additional treatment, either non-operative or operative. Because literature does not consistently report on surgery-related complications after shoulder arthroscopy, it is impossible to draw valid conclusion on the incidence of complications. The most common complication is the postoperative shoulder stiffness, which is reported to occur in 2.6%–23.3% of cases.[81] The overall infection rate for all arthroscopic shoulder procedures is 0.27%, being highest for rotator cuff repair (0.29%) and lowest for capsulorrhaphy (0.16%).[82] Rate for neurovascular complications is 0.4%–3.4%.[81] Taking into account that diagnostic arthroscopy does not include any shaving, burning or additional procedure, it is much less traumatic than the active treatment arm. In addition, there will be no foreign materials left in the shoulder after the procedure.

Considering the aforementioned issues, we will assume that incidence of complications in the diagnostic arthroscopy group will be smaller than those reported for arthroscopic procedures. The main concern is if the unrepaired tear becomes larger by time, retracts and induces irreversible fatty degeneration of the scapular musculature. There are no high-quality studies on the natural course of an acute cuff tear. There are only a few studies available on the evolution of a non-operatively

Continued

Box 3 Continued

treated supraspinatus tendon tear.[1 69 75] Accordingly, significant short-term tear size progression is unlikely. Overall, we consider the risk profile to be acceptable.

Avoiding deception

Patients are openly explained the placebo design of the trial and told what it means. They get oral and written information concerning the trial, and a written informed consent is obtained. The operating doctor and staff (who are the only ones who know the allocated intervention group) will not meet with patient after the operation to avoid compromise in blinding. The follow-up visits are carried out by the blinded physiotherapist and doctor.

Potential significant change to clinical practice

The results of this trial will directly affect the decision-making process worldwide. If the results show that repair and physiotherapy is clinically superior to placebo surgery and physiotherapy, it corroborates that the tendon repair has an important effect in the treatment of an acute cuff tear. However, if placebo surgery group is superior or the difference between groups is not clinically significant, there is no justification for a tendon repair in the treatment of an acute supraspinatus tear. Consequently, conservative treatment should be advocated taking into account the higher costs and greater risk for complications in the operative treatment.

Benefits to the patients in the placebo group

All patients in the placebo group do get placebo surgery and supervised specific exercise therapy delivered by a physiotherapist, like the patients in the cuff repair group. To our knowledge, there is no published study on conservative treatment of traumatic rotator cuff tears. According to prospective cohort study and open-label RCTs on atraumatic cuff tears, conservative treatment yields clinically significant improvement. Second the patients in the placebo group will probably experience a positive meaning response due to the trial design. Third, the patients in the placebo group get a diagnostic arthroscopy prior to randomisation. Their glenohumeral joint is evaluated, and any encountered pathology is documented, and if, for example, a total subscapularis or infraspinatus tear or a partial-thickness tear is verified, patient is excluded from the trial and treated accordingly. Although the MRI has a good diagnostic accuracy on full-thickness rotator cuff tears, the specificity and sensitivity is not 100%.[83] In addition, patients in clinical trials have many potential benefits over standard care with respect to additional monitoring (including imaging, clinic visits and interviews) and ongoing attention and care, all of which would be likely to have value by itself.[84] Furthermore, after a surgical placebo intervention, patients report significant improvement for a prolonged period of time, and the effect does not seem to change significantly with time.[85] If at the end of trial the placebo group is equal or superior to tendon repair group, the patients in the placebo group will benefit by getting a smaller operation with a minor risk for complication, and no foreign material is left in their body.

distinguished from each other. Furthermore, we exclude all patients with severe degenerative imaging findings as well as patients with preceding symptoms to ensure inclusion of previously subjectively 'healthy' shoulders only.

The aim and ultimate value of the ACCURATE is to demonstrate the true efficacy of an arthroscopic rotator cuff repair in patients with trauma-related full-thickness supraspinatus tendon tear with acute symptoms. If the repair is effective and superior to PS doctors have a strong scientific support to recommend surgery when counselling these patients.

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