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Partial rotator cuff tear repair trial

Submission date
22/06/2020

Recruitment status
Stopped

Registration date
02/07/2020

Overall study status
Stopped

Last Edited
27/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Rotator cuff tears are tendon tears in the shoulder that cause pain, weakness and loss of movement. These tears can be full tears through the whole tendon or only partway through - a partial tear. People affected have problems with day-to-day activities, work, recreation and sleep. Partial tears are first treated in the NHS with physiotherapy and often a steroid injection. Patients who do not get better with these treatments may then choose to have surgery. This study aims to assess if surgical repair of partial tears, in patients with persistent pain despite physiotherapy, is effective. The study is important because, even though rotator cuff problems are the most common cause of shoulder pain and disability, it remains unknown how best to treat them and whether surgery has any extra value. In particular, it is not known whether repairing partial tears prevents bigger full tears and worsening problems. Surgery for full tears is one of the most common shoulder operations in the UK. Prevention of full tears was identified as important by patients and doctors in the 2015 James Lind Alliance Priority Setting Partnership (PSP) for Surgery for Common Shoulder Conditions (4 of the top 10 priorities were about rotator cuff problems). The main aim of this study is therefore to find out if repairing these partial tears is effective, provides lasting benefit and prevents bigger tears.

Who can participate?
Patients aged over 18 with a partial thickness tear

What does the study involve?
The study will compare two similar procedures: arthroscopic debridement with arthroscopic repair (ADAR) which involves arthroscopic (keyhole) surgery to debride (shave away inflamed tissue, rough tear edges, and bone spurs) and repair the tear. ADAR will be compared to arthroscopic debridement only (ADO) which involves arthroscopic surgery to debride only (shave away inflamed tissue, rough tear edges, and bone spurs) without any repair.
For each participant the type of surgery received will be chosen at random by a computer programme. Participants will complete a questionnaire at five timepoints. One will be completed before surgery takes place. Four more questionnaires will be sent at 6, 12, 24 months and 5 years after surgery. Each questionnaire takes around 10 minutes to fill out and will be completed at home; online or on paper according to participant preference. At the 5-year timepoint, as well as asking participants to complete a questionnaire, the researchers will

request routine information on further treatment or problems relating to the shoulder from NHS Digital (Hospital Episodes Statistics). In addition to the questionnaires, 2 years after surgery, participants will be asked to undergo an MRI scan at their local hospital.

What are the possible benefits and risks of participating?
Outside of the usual risks associated with surgery and anaesthetic, there are no anticipated risks or disadvantages to participating in the study. Both procedures are already performed routinely in the NHS, and there is no expected difference in the risk between them, or between treatment outside of the study. The main benefit of taking part in the study will be the information the participant provides which will help to improve treatment in the future. The results of the study are likely to benefit future NHS patients with shoulder complaints.

Where is the study run from?
Surgical Intervention Trials Unit (SITU) and Oxford Clinical Trials and Research Unit (OCTRU) at the Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS), University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2020 to September 2027

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
SITU-NDORMS Team, situ@ndorms.ox.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283908

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR128043, PID15009

Study information

Scientific Title
The clinical and cost-effectiveness of surgical repair of partial rotator cuff tears in patients with subacromial shoulder pain: a comparison of surgical repair versus surgery with no repair

Acronym
PRoCuRe

Study objectives
In patients with a suspected partial-thickness rotator cuff tear and subacromial shoulder pain listed for arthroscopic surgery, is ADAR (Arthroscopic Debridement and Arthroscopic Repair) more beneficial than ADO (Arthroscopic Debridement Only) as measured by pain reduction and functional restoration at 24 months post-operation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2021, London Central REC (London - Central Research Ethics Committee, 3rd Floor, Barlow House, 4, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8225; londoncentral.rec@hra.nhs.uk), ref: 21/LO/0081

Study design
Multi-centre parallel patient blinded two-arm randomized controlled trial with integrated QuinteT Recruitment Intervention (QRI) to support recruitment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Subacromial pain and suspected partial-thickness rotator cuff tear

Interventions
PRoCuRe is a randomised controlled trial with 1:1 allocation. Patient eligibility for randomisation will be confirmed during surgery. Eligible patients will be randomised in theatre to receive one of the two possible interventions: Arthroscopic Debridement and Arthroscopic Repair (ADAR) or Arthroscopic Debridement Only (ADO).

Arthroscopic Debridement with Arthroscopic Repair (ADAR) involves arthroscopic (keyhole) surgery to debride (shave away inflamed tissue, rough tear edges, and bone spurs) and repair the tear. ADAR will be compared to Arthroscopic Debridement Only (ADO) which involves arthroscopic surgery to debride only (shave away inflamed tissue, rough tear edges, and bone spurs) without any repair.

For each participant the type of surgery received will be chosen at random by a computer programme. Participants will undertake a questionnaire at 5 timepoints. One will be completed before surgery takes place (baseline). Four more questionnaires will be sent at 6, 12, 24 months and 5 years after surgery. Each questionnaire takes around 10 minutes to fill out and will be completed at home; online or on paper according to participant preference. At the 5-year timepoint, as well as asking participants to complete a questionnaire, the researchers will request routine information on further treatment or problems relating to the shoulder from NHS Digital (Hospital Episodes Statistics). In addition to the questionnaires, 2 years after surgery, participants will be asked to undergo an MRI scan at their local hospital.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain and function measured using the Oxford Shoulder Score (OSS) at 24 months post-randomisation

Secondary outcome measures
1. Pain and function measured using the Oxford Shoulder Score (OSS) at baseline, 6, 12 months, and 5 years post-randomisation
2. Quality of life measured using EQ-5D-5L at baseline, 6, 12, 24 months and 5 years post-randomisation
3. Patient use of health resources assessed using a health resource use questionnaire at 6, 12, and 24 months post-randomisation
4. Patient satisfaction and perception assessed using satisfaction and perception questionnaire at 6, 12, and 24 months post-randomisation
5. Progression to full-thickness cuff tears assessed through MRI imaging at 24 months post-randomisation
6. Readmission for further surgery and associated costs assessed by routinely collected observational hospital data (HES) at 5 years post-randomisation

Overall study start date
01/01/2020

Completion date
30/09/2027

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Willing and able to provide informed consent
3. MRI or USS suggesting a Partial Thickness Tear (PTT) diagnosis is Supraspinatus
4. An understanding of the English language sufficient to receive written and verbal information about the trial, its consent process and complete study questionnairesMRI or USS suggesting a PTT diagnosis in Supraspinatus
Inclusion Criteria for randomisation (confirmed in surgery)
5. PTT more than 50% tendon thickness confirmed in Supraspinatus during arthroscopy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
It is anticipated that, to achieve the target 270 randomised participants, around 386 patients will be recruited

Key exclusion criteria
1. Patient has not had 6 months of physiotherapy
2. Patient has not had at least one steroid injection
3. Steroid injection within 6 weeks of planned surgery date
4. No Partial Thickness Tear (PTT)
5. PTT less than 50% tendon thickness
6. Any full-thickness tears on imaging or at surgery
7. Inflammatory arthritis (e.g. rheumatoid)
8. Glenohumeral osteoarthritis
9. Current active malignancy of any kind
10. Tears associated with acute fractures
11. Tears associated with shoulder dislocations
12. Upper limb neurological deficit on either side
13. Unable to undergo MRI
14. Unable to complete the written follow-up questionnaires

Date of first enrolment
01/07/2021

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopedic Centre, Oxford University Hospitals NHS Foundation Trust
Nuffield Orthopedic Centre
Windmill Road
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Oxford
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OX3 7LD

Sponsor information

Organisation
University of Oxford

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+44 (0)1865 289885
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents such as the study protocol and statistical analysis plan will be available.

Intention to publish date
01/11/2028

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the study closing early with minimal data collected.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Preprint results		12/06/2023	01/11/2023	No	No