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Can Shoulder Arthroscopy Work: What is the clinical and cost effectiveness of arthroscopic sub-acromial decompression surgery for patients with sub-acromial Pain?

Submission date
22/06/2012

Recruitment status
No longer recruiting

Registration date
22/06/2012

Overall study status
Completed

Last Edited
12/01/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Shoulder problems causing pain and decreased function are very common. Many of these problems are related to the rotator cuff tendons (tissue that attaches muscle to bone). Shoulder arthroscopy (key-hole surgery) is a common treatment for this pain. Treatment can involve an arthroscopic sub-acromial decompression (ASAD) - an operation similar to arthroscopy that also involves shaving off a small part of the bone above the tendons. The procedure is widely used despite limited evidence of any effectiveness. This study will compare ASAD against investigation shoulder arthroscopy (without bone spur removal/decompression) to indicate whether spur removal is really necessary and in turn, assess the effectiveness of the ASAD procedure. Both surgical treatments will be compared to a control (active monitoring with specialist reassessment [AMSR]) group to indicate whether surgery in general is effective for patients with sub-acromial pain.

Who can participate?
300 men and women with sub-acromial shoulder pain.

What does the study involve?
Patients will be randomly allocated into one of three treatment groups: AMSR, arthroscopy and ASAD. All patients will be assessed at three appointments over 12 months. The baseline assessment will occur when they first enter the study; they will then have follow-up assessments at 6 and 12 months. Patients allocated to the AMSR will be reassessed at 3, 6 and 12 months.

What are the possible benefits and risks of participating?
We cannot guarantee any benefit to participants, any of the three treatments being compared would be a good option until the study results are known. The main benefit of taking part is the information gained may help to improve future patient care. There are no anticipated risks to participating in this study, although there will be the usual risks associated with surgery and anaesthesia for participants allocated to the surgical options.

Where is the study run from?
This study is organised by a team based at the Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences (NDORMS) at the University of Oxford.

When is the study starting and how long is it expected to run for?
We aim to start recruiting patients in July 2012 and follow-up will be completed by the end of March 2017.

Who is funding the study?
Arthritis Research UK.

Who is the main contact?
Ms Naomi Cummings, CSAW Trial Co-ordinator
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Study website
http://www.situ.ox.ac.uk/surgical-trials/csaw

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01623011

Secondary identifying numbers
12104

Study information

Scientific Title
What is the clinical and cost effectiveness of arthroscopic sub-acromial decompression surgery for patients with sub-acromial Pain? A randomised trial

Acronym
CSAW

Study objectives
Shoulder problems causing pain and decreased function are very common. Many of these problems are related to the rotator cuff tendons. Shoulder arthroscopy surgery (keyhole surgery) is a common treatment for this pain. This can involve an Arthroscopic Subacromial Decompression (ASAD) an operation used to remove bony spurs which may be the cause of the pain. This procedure is widely used despite limited evidence of any effectiveness. This is a randomised controlled trial that will compare ASAD against an investigational shoulder arthroscopy (without spur removal/decompression) to indicate whether spur removal is really necessary and in turn, assessing the effectiveness of the ASAD procedure. Both surgical interventions are routine and will mirror each other except for the spur removal element.

Both treatments will be compared against a control (non operative management with specialist reassessment) group to indicate whether surgery in general is effective for patients with subacromial pain. Patients randomised to either of the surgical options will be blinded to the type of surgery they have.

This is a multicentre trial taking place in 10 centres in England and Wales. Two satellite studies will also take place. One will involve a subset of patients undergoing MRI scans to examine the effects of their shoulder pain on their brain transmissions. The other will involve collecting tissue samples from patients undergoing surgery.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=12104

On 23/07/2015 the overall trial end date was changed from 31/03/2016 to 31/03/2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire Research Ethics Committee B, 12/SC/0028; First MREC approval date 16/03/2012

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.situ.ox.ac.uk/develop/health-economics/csaw-pis-v5.pdf

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Active Monitoring: Patients will be advised that they will undergo active monitoring in the short term. They will attend a reassessment appointment 3 months after entering the study. Here, they will be asked to complete questionnaires related to their shoulder pain and undergo a clinical assessment for their shoulder.

ASAD Surgery, Arthroscopic Sub-acromial Decompression: The procedure is performed under general anaesthetic. Skins incisions are made for the introduction of the arthroscope and required instruments. The procedure involves insertion of the arthroscope into the glenohumeral joint where the joint surface is inspected along with the intra-articular portion of the long head of biceps and the joint surface of the rotator cuff tendons. Once this has been performed the arthroscope is removed and inserted into the sub-acromial joint.

Shoulder Arthroscopy, Arthroscopy Only: This is the surgical comparison group. The procedure is performed under general anaesthetic. Patients will undergo a routine investigational arthroscopy. The operation will be performed in exactly the same manner as Group ASAD. The exception is they will not undergo the decompression (bone spur removal) and the arthroscope is not introduced into the sub-acromial bursa. Tissues will be visualised and the joint will be washed out. The time spent in theatre will be similar to th; Follow Up Length: 12 month(s)

Intervention Type
Procedure/Surgery

Primary outcome measure

Oxford Shoulder Score; Timepoint(s): 6 months post randomisation

Secondary outcome measures
1. Constant Murley Score; Timepoint(s): 6 and 12 months post randomisation
2. EQ5D; Timepoint(s): 6 and 12 months post randomisation
3. Hospital Anxiety and Depression Scale (HADS) Questionnaire; Timepoint(s): 6 and 12 months post randomisation
4. Pain DeTECT Questionnaire; Timepoint(s): 6 and 12 months post randomisation
5. Quantitative Sensory Testing; Timepoint(s): 6 and 12 months post randomisation

Overall study start date
01/07/2012

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Sub-acromial pain of at least 3 month duration
2. Diagnosis by Consultant of sub-acromial pain or partial thickness rotator cuff tear
3. Has had an Magnetic Resonance Imaging (MRI) or Ultrasound scan to rule out alternative pathology
4. Able to undergo arthroscopic surgery
5. Physiotherapy that includes a remedial exercise regime
6. at least 1 previous cortisone injection but not more than 3
7. Inclusion criteria for the FMRI Sub Study is that they must be able to undergo an MRI scan according to safety regulations outlined in the MRI Safety Questionnaire.; 8. Target Gender: Male & Female; Upper Age Limit 75 years ; Lower Age Limit 35 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. Full thickness rotator cuff tear (diagnosed/eliminated using Ultrasound or MRI)
2. Undergone previous surgery on affected shoulder
3. Diagnosed rheumatoid arthritis or other inflammatory disorder
4. Symptomatic,cervical spine pathology
5. Previous septic arthritis
6. History of radiotherapy on affected shoulder side
7. Patients who have a strong preference for one treatment over another

8. Patients from the Nuffield Orthopaedic Centre, Oxford who are recruited to the main study will be excluded from the Neuroimaging MRI Scans if any of the following MRI contraindications are present:
8.1. Metal in their body, implants (may cause injury to the participant and produce artefacts on MR scans)
8.2. History of severe claustrophobia (may cause discomfort inside the MRI scanner)
8.3. Pregnancy
8.4. Taking medication that may influence brain function

Date of first enrolment
01/07/2012

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Oxford
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OX3 7LD

Study participating centre
32 recruiting centres
United Kingdom
-

Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	09/05/2015		Yes	No
Results article		27/01/2018	12/01/2023	Yes	No