

Sub-acromial spacer for tears affecting rotator cuff tendons (START:REACTS)

Submission date 05/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Current plain English summary as of 06/04/2020:

Background and study aims

Within the shoulder there are a group of small muscles and tendons called the rotator cuff. Tears of the rotator cuff tendons are very common. They can be very painful and it can be difficult to move the shoulder normally. Many tears of the tendons can be repaired but some tears cannot. When a tear cannot be repaired, one common treatment is a keyhole operation to clear space around the tendons and remove the painful tissue. This is called an arthroscopic debridement. It is not known whether this operation helps in every case, but it is low risk and is thought to benefit most people with rotator cuff tears. A new device has recently been introduced in the UK with the aim of improving outcomes from surgery for this condition. It is a balloon made out of a biodegradable synthetic material (free of animal products), called the InSpace balloon. It is inserted at the end of an arthroscopic debridement operation and is filled with water. It is thought to act as a cushion inside the joint. It dissolves after about three months, by which time the patient has had a chance to strengthen the other muscles to give a longer lasting effect. It is not yet known whether it is any better or worse than the standard arthroscopic debridement operation. The aim of this study is to find out whether it is better to have an arthroscopic debridement operation, or the same operation with the addition of the InSpace balloon, in patients with a tear of the rotator cuff muscles that cannot be repaired. The National Institute of Health and Care Excellence (NICE) has studied the balloon and decided that it should only be used in research to determine if it works. The study will look at which operation is best at reducing pain and improving movement, strength, and quality of life, and whether the balloon is worth the additional cost.

Who can participate?

Patients with rotator cuff tears that cannot be repaired

What does the study involve?

Participants are randomly allocated to be treated with arthroscopic debridement either with or without the InSpace balloon. Arthroscopic debridement is a keyhole operation involving two or three small incisions (cuts) mostly 1cm, the biggest is about 1.5cm, around the shoulder. The surgeon looks around the main shoulder joint, they take away loose or inflamed tissue, and

shave some of the bone to create space to allow more movement and reduce pain. The surgeon may also choose to cut the end of the biceps tendon, which can help with pain. It is a low risk operation and most people are able to go home the same day. The recovery from this procedure takes between 6 weeks and 3 months. Arthroscopic debridement with the InSpace balloon is the same operation as an arthroscopic debridement, but at the end of the procedure the InSpace balloon is inserted. The balloon is made of a biodegradable material and takes only a few minutes to insert. As the incisions and postoperative physiotherapy are the same, neither the participant nor the person assessing the results know which treatment has been given. This ensures a fair and unbiased comparison. Participants are contacted at 3, 6 and 12 months to collect outcome measures as part of the follow-up questionnaires. Questionnaires are also used to assess disability, quality of life, and costs, including lost earnings. A sub-group of 56 participants in the main study will also have shoulder scans taken 8 weeks and 6 months after surgery to assess the way the balloon is thought to work. Two years after the operation participants complete a questionnaire about their shoulder and general health.

What are the possible benefits and risks of participating?

There are no specific benefits of taking part. Both treatments are designed to help the shoulder recover. By taking part in the study participants are helping to decide about the best treatment for people in the future. There are general risks with any shoulder operation, such as infection, stiffness, frozen shoulder (a very stiff shoulder, which recovers), worsened pain, blood clots, wound healing problems or anaesthetic problems (including death). These risks are all small and are from the operation that everyone in this study has. The additional risk from taking part in the study is also small. The shoulder balloon can be put in the wrong place, or move after the operation and occasionally may have to be surgically removed, or can cause inflammation in the shoulder. These problems are uncommon and have occurred in less than 5% (1 in 20) of people who have had the balloon so far.

Where is the study run from?

The study is run from the Warwick Clinical Trials Unit – University of Warwick (UK)

When is the study starting and how long is it expected to run for?

February 2018 to December 2021

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Elke Gemperle Mannion

start@warwick.ac.uk

Previous plain English summary:

Background and study aims

Within the shoulder there are a group of small muscles and tendons called the rotator cuff. Tears of the rotator cuff tendons are very common. They can be very painful and it can be difficult to move the shoulder normally. Many tears of the tendons can be repaired but some tears cannot. When a tear cannot be repaired, one common treatment is a keyhole operation to clear space around the tendons and remove the painful tissue. This is called an arthroscopic debridement. It is not known whether this operation helps in every case, but it is low risk and is thought to benefit most people with rotator cuff tears. A new device has recently been

introduced in the UK with the aim of improving outcomes from surgery for this condition. It is a balloon made out of a biodegradable synthetic material (free of animal products), called the InSpace balloon. It is inserted at the end of an arthroscopic debridement operation and is filled with water. It is thought to act as a cushion inside the joint. It dissolves after about three months, by which time the patient has had a chance to strengthen the other muscles to give a longer lasting effect. It is not yet known whether it is any better or worse than the standard arthroscopic debridement operation. The aim of this study is to find out whether it is better to have an arthroscopic debridement operation, or the same operation with the addition of the InSpace balloon, in patients with a tear of the rotator cuff muscles that cannot be repaired. The National Institute of Health and Care Excellence (NICE) has studied the balloon and decided that it should only be used in research to determine if it works. The study will look at which operation is best at reducing pain and improving movement, strength, and quality of life, and whether the balloon is worth the additional cost.

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Where is the study run from?

1. University Hospitals Coventry and Warwickshire NHS Foundation Trust (UK)
2. Royal Devon and Exeter NHS Foundation Trust (UK)

3. North Tees and Hartlepool NHS Foundation Trust (UK)
4. Guy's and St. Thomas' NHS Foundation Trust (UK)
5. The Robert Jones and Agnes Hunt NHS Foundation Trust (UK)
6. Royal Liverpool and Broadgreen University Hospitals NHS Trust (UK)
7. London North West Healthcare NHS Trust (UK)
8. The Royal Orthopaedic Hospital NHS Foundation Trust (UK)
9. Cambridge University Hospitals NHS Foundation Trust (UK)
10. North Bristol NHS Trust (UK)
11. Stockport NHS Foundation Trust (UK)
12. Morriston Hospital (UK)
13. Royal United Hospitals Bath NHS Foundation Trust (UK)
14. Queen Elizabeth University Hospital (UK)
15. Cardiff and the Vale Orthopaedic Centre (CAVOC) (UK)
16. Wrightington, Wigan and Leigh NHS Foundation Trust (UK)
17. Shrewsbury and Telford NHS Foundation Trust (UK)
18. Royal Gwent Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2018 to December 2021

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

Who is the main contact?
Dr Elke Gemperle Mannion
start@warwick.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Elke Gemperle Mannion

Contact details
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Additional identifiers

Protocol serial number
37199

Study information

Scientific Title

Sub-acromial spacer for Tears Affecting Rotator cuff Tendons (START:REACTS): a randomised, efficient, adaptive clinical trial in surgery

Acronym

START:REACTS

Study objectives

The aim of this study is to compare arthroscopic debridement (the standard treatment) to arthroscopic debridement with the InSpace balloon on shoulder function, pain and quality of life following shoulder surgery for rotator cuff tears that cannot be repaired.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands – Coventry and Warwickshire Research Ethics Committee, 13/02/2018, ref: 18 /WM/0025

Study design

Randomised; Interventional; Design type: Treatment, Device, Imaging, Complex Intervention, Management of Care, Surgery, Rehabilitation

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

Interventions

Current interventions as of 06/04/2020:

Participants will be randomly allocated to arthroscopic debridement (the standard treatment) or arthroscopic debridement with the InSpace balloon. As the incisions and postoperative physiotherapy are the same, neither the participant nor the person assessing the results will know which treatment has been given. This will ensure a fair and unbiased comparison. Participants will be contacted at 3, 6, and 12 months for the follow-up questionnaires are used to assess disability, quality of life, and costs, including lost earnings. A group of 56 participants will also have shoulder scans taken 8 weeks and 6 months after surgery, to assess the way the balloon is thought to work. This study will determine whether the use of this device improves shoulder function, pain and quality of life following shoulder surgery for rotator cuff tears that cannot be repaired.

Previous interventions:

Patients will be randomly allocated to arthroscopic debridement (the standard treatment) or arthroscopic debridement with the InSpace balloon. As the incisions and postoperative physiotherapy are the same, neither the patient nor the person assessing the results will know which treatment has been given. This will ensure a fair and unbiased comparison. Patients will be seen at 3, 6, and 12 months to measure strength, range of motion and pain. Questionnaires are used to assess disability, quality of life, and costs, including lost earnings. A group of 56 patients will also have shoulder scans taken 6 weeks and 6 months after surgery, to assess the way the balloon is thought to work. This study will determine whether the use of this device improves shoulder function, pain and quality of life following shoulder surgery for rotator cuff tears that cannot be repaired.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

InSpace balloon

Primary outcome(s)

Current primary outcome measure as of 06/04/2020:

The Oxford Shoulder Score (OSS) at 12 months after surgery.

As participants are randomised during surgery this means 12 months after randomisation. The original study design was based around the Constant score, which is a face to face measure taken in hospital clinics. In light of the coronavirus outbreak in March 2020, the researchers, supported by the trial's Steering and Data Monitoring Committees as well as the funders, decided to revise the primary outcome from the Constant Score to the Oxford Shoulder Score (OSS) which is a Patient Reported Outcome Measure (PROM). This will enable the continuation of the study without exposing participants to unnecessary risks during the height of the pandemic. The Oxford Shoulder Score is simple to complete and has proved to be valid and reliable in determining the outcome from shoulder surgery.

Previous primary outcome measure:

Shoulder function measured with the Constant-Murley score collected 12 months after surgery (note that in this study, randomisation occurs at the time of surgery, so this is also 12 months after randomisation)

Key secondary outcome(s)

Current secondary outcome measures as of 06/04/2020:

1. The Oxford Shoulder Score (OSS) at baseline, three, six, and 24 months
2. Shoulder function is measured using the Constant-Murley score at baseline, 3 and 6 months and 12 months
3. Range of pain-free shoulder movement will be measured with a (12.5 in) goniometer at

baseline, 3, 6 and 12 months

4. Strength of the shoulder in abduction and flexion will be measured at baseline, 3, 6 and 12 months using a supplied IsoForceControl EVO2 dynamometer (Herkules Kunststoff, Switzerland)
5. Patient reported functional outcome will also be measured using the Western Ontario Rotator Cuff Index. This is a disease specific questionnaire looking at physical symptoms, sports /recreation, work, lifestyle and emotions. This will be collected at baseline, 3, 6 and 12 months
6. Health utility will be measured using the 5Q-5D-5L. This will be collected at baseline, 3, 6 and 12 and 24 months
7. Healthcare resource – a set of questions to collect information associated with healthcare, personal and social services costs related to the interventions being compared. This will be collected at baseline, 3, 6 and 12 months
8. Patient global assessment of change (PGIC) will be measured on a 7-point scale at 3, 6 and 12 and 24 months
9. Analgesia use – this will be a set of questions to assess use of analgesia and frequency by the participant. This will be collected at 3, 6 and 12 months
10. MRI Scans 56 for participants in the MRI sub-study eight weeks and six months post-surgery)
11. Adverse events will be collected from site reports as they occur throughout the first 12 months after randomisation, and from participants in the 3, 6 and 12 month questionnaires

Previous secondary outcome measures:

1. Shoulder function measured using the Constant-Murley score at baseline, 3 and 6 months
2. Range of pain-free shoulder movement measured with a goniometer at baseline, 3, 6 and 12 months
3. Strength of the shoulder in abduction and flexion measured at baseline, 3, 6 and 12 months
4. Patient-reported functional outcome measured using the Oxford Shoulder Score at baseline, 3, 6 and 12 months
5. Patient-reported functional outcome measured using the Western Ontario Rotator Cuff Index at baseline, 3, 6 and 12 months
6. Health utility measured using the 5Q-5D-5L at baseline, 3, 6 and 12 months
7. Resource use, measured using a set of questions to collect information associated with healthcare, personal and social services costs related to the interventions being compared, collected at baseline, 3, 6 and 12 months
8. Patient global assessment of change (PGIC) measured on a 7-point scale at 3, 6 and 12 months
9. Analgesia use, measured using a set of questions at 3, 6 and 12 months

Completion date

31/12/2021

Eligibility

Key inclusion criteria

Male and female patients presenting themselves to one of the participating hospitals with a potentially irreparable rotator cuff tendon tear will be assessed for eligibility into the study. The eligibility criteria are:

1. Rotator cuff tear deemed by the treating clinician to be technically irreparable (to be confirmed intra-operatively)

2. Intrusive symptoms (pain and loss of function) which in the opinion of the treating clinician warrants surgery
3. Non-operative management has been unsuccessful

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

117

Key exclusion criteria

1. Advanced gleno-humeral osteoarthritis on pre-operative imaging (in the opinion of the treating clinician). Advanced gleno-humeral OA may be interpreted as Kellgren Lawrence grade 3 or 4 changes on routine pre-operative radiographs(64), or the MRI equivalent if radiographs have not been taken
2. Subscapularis deficiency*, defined as a tear involving more than the superior 1cm (approximately) of the subscapularis if repaired, or any tear that is not repaired. Minor, repairable, upper border tears are common and a repairable upper-border tear is not considered a contra-indication by the manufacturer
3. The treating surgeon determines that interposition grafting or tendon transfers are indicated. Some surgeons prefer to treat younger, more active patients with operations designed to restore or replace rotator cuff function. There is no established age criterion for this, however and the decision is based on multiple factors including age, co-morbidities, occupation, level of activity, and surgeon preference
4. Pseudoparalysis, as determined by the treating clinician
5. Unrelated, symptomatic ipsilateral shoulder disorder that would interfere with strength measurement or ability to perform rehabilitation
6. Other neurological or muscular condition that would interfere with strength measurement or ability to perform rehabilitation, in the opinion of the treating clinician
7. Previous proximal humerus fracture that could influence shoulder function, as determined by the treating clinician
8. Previous entry into the present trial (i.e. other shoulder)
9. Unable to complete trial procedures
10. Age under 18
11. Unable to consent to the trial
12. Unfit for surgery as defined by the treating clinician

Date of first enrolment

01/06/2018

Date of final enrolment

30/07/2020

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

University Hospitals Coventry and Warwickshire NHS Foundation Trust

Clifford Bridge Rd

Coventry

United Kingdom

CV2 2DX

Study participating centre

Royal Devon and Exeter NHS Foundation Trust

Royal Devon and Exeter Hospital

Barrack Rd

Exeter

United Kingdom

EX2 5DW

Study participating centre

North Tees and Hartlepool NHS Foundation Trust

University Hospital of Hartlepool

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United Kingdom

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Study participating centre

Guy's and St Thomas' NHS Foundation Trust

Guy's Hospital

Great Maze Pond

London

United Kingdom

SE1 9RT

Study participating centre

The Robert Jones and Agnes Hunt NHS Foundation Trust

Gobowen

Oswestry

United Kingdom

SY10 7AG

Study participating centre

London North West Healthcare NHS Trust

Northwick Park Hospital

Watford Road

Harrow

United Kingdom

HA1 3UJ

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Addenbrooke's Hospital

Hills Road

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CB2 0QQ

Study participating centre

North Bristol NHS Trust

Southmead Hospital

Southmead Road

Westbury-on-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre

Cardiff and the Vale Orthopaedic Centre (CAVOC)

University Hospital Llandough

Penlan Road, Penarth

Cardiff

United Kingdom

CF64 2XX

Study participating centre

Royal Gwent Hospital

Cardiff Rd
Newport
United Kingdom
NP20 2UB

Study participating centre**The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust**

Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**

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Study participating centre**Royal National Orthopaedic Hospital**

Brockley Hill
Stanmore
United Kingdom
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Study participating centre**Salisbury NHS Foundation Trust**

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Salisbury
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Study participating centre**University Hospital Southampton NHS Foundation Trust**

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B71 4HJ

Study participating centre
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Tonbridge Rd
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Nevil Hall Hospital
Brecon Rd
Abergavenny
United Kingdom
NP7 7EG

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust

ROR
<https://ror.org/025n38288>

Organisation
University of Warwick

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/61/18

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	protocol	21/04/2022	22/04/2022	Yes	No
Results article		01/08/2023	10/05/2024	Yes	No
Protocol article		01/05/2020	27/11/2020	Yes	No
HRA research summary	study design investigation		28/06/2023	No	No
Other publications		09/12/2019	10/12/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results	Study website		22/04/2022	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes