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

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
06/04/2018

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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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What are the possible benefits and risks of participating?
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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

Study website
https://warwick.ac.uk/fac/sci/med/research/ctu/trials/startreacts

Contact information

Type(s)
Scientific

Contact name
Dr Elke Gemperle Mannion

Contact details
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University of Warwick
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Coventry
United Kingdom
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-
start@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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.

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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 measure
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.

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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)

Secondary outcome measures

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 Kunstoff, 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

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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

Overall study start date
01/02/2018

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 221; UK Sample Size: 221

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
England

United Kingdom

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
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

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
Cambridge
United Kingdom
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
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore

United Kingdom
HA7 4LP

Study participating centre
Salisbury NHS Foundation Trust
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
West Suffolk NHS Foundation Trust
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre

Kingston Hospital NHS Foundation Trust
Galsworthy Road
Kingston Upon Thames
United Kingdom
KT2 7QB

Study participating centre
Nottingham University Hospitals NHS Foundation Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Sandwell and West Birmingham NHS Trust
Lyndon
West Bromwich
United Kingdom
B71 4HJ

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
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

Sponsor details
Clifford Bridge Road
Coventry
England
United Kingdom
CV2 2DX

Sponsor type
Hospital/treatment centre

Website
http://www.uhcw.nhs.uk/

ROR
https://ror.org/025n38288

Organisation
University of Warwick

Sponsor details
Warwick Clinical Trials Unit
CSRL
UHCW
Coventry
England
United Kingdom
CV2 2DX
-
start@warwick.ac.uk

Sponsor type
University/education

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan

1. Protocol is not available for publication yet. It is expected to be available on the NIHR website: https://www.journalslibrary.nihr.ac.uk
2. Planned publication of the results in a high-impact peer reviewed journal. Publication intended for December 2022, although as this is an adaptive study that timeline may alter.

Intention to publish date

21/04/2022

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?
Other publications	study design investigation	09/12/2019	10/12/2019	Yes	No
Protocol article	protocol	01/05/2020	27/11/2020	Yes	No
Plain English results			22/04/2022	No	Yes
Results article		21/04/2022	22/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/08/2023	10/05/2024	Yes	No