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Shoulder patch for rotator cuff tears

Submission date 15/10/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/12/2014	**Overall study status** Completed	
Last Edited 09/04/2020	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Rotator cuff tears (injury to the muscle or tendons which stabilise the shoulder) are one of the most common conditions affecting the shoulder. Small and medium sized rotator cuff tears can be managed with arthroscopic or keyhole surgery. Very large or massive tears are difficult to operate on and often have poor rates of healing. As a result surgeons have investigated the use of products to improve the outcome of surgery on massive tears. This study is testing a new product, called a patch, which is hoped will improve the outcome of surgery for massive rotator cuff tears. The patch provides a scaffold to support the muscles of the rotator cuff. Studies of rotator cuff surgery using similar patches have found that recovery is improved and there is a lower rate of post-surgical problems. The aim of this study is to look at the effect of the patch on the muscles in the shoulder and to look at whether using the patch improves pain and the clinical function of the shoulder after surgery.

Who can participate?
Participants who are at least 18 years old and with massive rotator cuff tears

What does the study involve?
Participants decide, together with their surgeon, whether to have patch-assisted surgery or standard treatment (either standard surgery or non-surgical management, which involves physiotherapy). They have a scan of their shoulder to look at the muscle damage in the shoulder before and after their treatment. Participants are also asked to fill in some questionnaires about their shoulder function and pain, before and after their treatment.

What are the possible benefits and risks of participating?
There is no direct benefit to people taking part in the study. However, it is hoped this study will provide information to help improve future treatment of massive rotator cuff tears. There are no direct risks to taking part in study. No medications, including analgesics or anti-inflammatories, are withheld and treatment (surgery or physiotherapy) is not delayed in any way. Participants have an MRI scan which can be claustrophobic, but the scan can be stopped at any time if the participant is not happy. MRI scans are very safe and give no radiation.

Where is the study run from?
Leeds Teaching Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2013 to June 2015

Who is funding the study?
1. Leeds Teaching Hospitals Charitable Foundation (UK)
2. NIHR Leeds Musculoskeletal Biomedical Research Unit (UK)

Who is the main contact?
Mr Roger Hackney
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Contact information

Type(s)
Scientific

Contact name
Dr Sarah Kingsbury

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02049684

Secondary identifying numbers
OR11/10063

Study information

Scientific Title
Shoulder PAtch for Rotator Cuff tears: an exploratory study

Acronym
SPARC

Study objectives
Use of a synthetic graft to augment rotator cuff repairs will provide better improvement of clinical function of the shoulder compared to conservative treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds West, 04/03/2013, ref: 13/YH/0030

Study design
Exploratory study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please email Dr Kingsbury (S.R.Kingsbury@leeds.ac.uk) to request a patient information sheet

Health condition(s) or problem(s) studied
Massive rotator cuff tears

Interventions
Patients will either undergo augmented patch-assisted rotator cuff repair or conservative treatment, which may include standard surgery or non-surgical management. Treatment decision will be made by the surgeon together with the patient.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Clinical outcomes (baseline, 6 weeks, 6 months):
1. Clinical examination
2. Shoulder function and pain, measured using the Oxford Shoulder Score, Shoulder Pain and Disability Index [SPADI], Constant Score
3. Quality of life, measured using EQ5D

Imaging outcomes:
1. MRI assessment of the supraspinatus, infraspinatous and subscapularis at baseline (pre-surgery) and 6 months post-surgery: Muscle volume, Goutallier score of muscle atrophy and fatty infiltration

Secondary outcome measures
This is an exploratory study, therefore there are no defined primary and secondary outcome measures

Overall study start date
17/09/2013

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. All patients who are considered for patch repair
2. Ultrasound or surgery confirming massive rotator full thickness tear
3. Unacceptable pain and disability following conservative treatment or previous surgery that has failed

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
68

Key exclusion criteria
1. History of infection
2. Neurological condition that affects the shoulder girdle
3. Presence of rotator cuff arthropathy
4. Subjects with inability to give informed consent
5. Pregnancy or lactation
6. Malignancy
7. Age less than 18 years
8. Subjects currently participating in other research studies
9. Subjects with the following contra-indications to MRI scanning will not have an MR scan but may be asked to have alternative imaging, for example ultrasound:
9.1. Pacemakers

9.2. Surgical clips within the head
9.3. Certain inner ear implants
9.4. Neuro-electrical stimulators
9.5. Metal fragments within the eye or head
9.6. Pregnant or breastfeeding women

Date of first enrolment
17/09/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Chapel Allerton Hospital
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
R&D department
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals Charitable Foundation (UK)

Funder Name
NIHR Leeds Musculoskeletal Biomedical Research Unit (UK)

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal within one year of trial completion

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sarah Kingsbury (s.r.kingsbury@leeds.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/04/2020	09/04/2020	Yes	No
HRA research summary			28/06/2023	No	No