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Does wearing a sling after keyhole tendon repair surgery in the shoulder give a better outcome than not wearing a sling?

Submission date
04/04/2019

Recruitment status
No longer recruiting

Registration date
17/04/2019

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
A rotator cuff tear is a damaged tendon around the shoulder. It can cause pain and weakness when moving the shoulder. It is commonly treated using keyhole surgery to reattach the torn tendon to the bone. After surgery, people go through a rehabilitation programme with a physiotherapist that lasts several months. This may involve wearing a sling after surgery. The aim of this study is to see whether a sling is beneficial or detrimental to your recovery after having your torn rotator cuff tendon repaired. Some surgeons prefer to rest the shoulder in a sling for several weeks after surgery to give the repaired tendon some time to heal. This may lead to stiffness due to lack of movement, and weakness of the other muscles around your shoulder, both of which require additional treatment from a physiotherapist. Modern tendon repair techniques are now stronger than ever and a period of rest may no longer be necessary. It is also known that the quality of healing may be improved by early movement.

Who can participate?
Patients undergoing a keyhole repair of a torn tendon in the shoulder

What does the study involve?
Participants' shoulder movements are measured and they complete some questionnaires. They also have a scan 6 months after surgery to check whether the repaired tendon has healed. After surgery, if the surgeon is satisfied that the repair is sound, participants are given an individualised exercise programme by the physiotherapist. This is selected at random from one of two options. One involves wearing a sling for 1-2 days (maximum 1 week), and the other involves using a sling for 4 weeks after surgery. Participants have regular visits to the physiotherapist to monitor their progress over the following 12 months using standard outcome scores, measure their range of movement, and also measure the electrical activity in their shoulder muscles. A scan of their shoulder is also performed after 6 months to determine whether the tendon has healed.

What are the possible benefits and risks of participating?
It is not yet known whether patients benefit more from shorter- or longer-term sling use after

rotator cuff repair. Participation will help to determine the answer to this and if participants are allocated to the treatment that is found to be more successful, then they may derive a benefit.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to August 2020

Who is funding the study?
British Elbow and Shoulder Society (UK)

Who is the main contact?
Chris Peach
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT03913611

Protocol serial number
4.1

Study information

Scientific Title

Traditional versus accelerated rehabilitation programmes following double-row rotator cuff repair: a randomised trial to compare patient outcomes and structural failure rates

Acronym
S-START

Study objectives
There is a difference in Oxford Shoulder Score 3 months after rotator cuff repair in patients who have an accelerated rehabilitation programme versus traditional rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/04/2019, West of Scotland REC 5 (West of Scotland Research Ethics Service, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SW; Tel: +44 (0)141 232-1804; Email: WoSREC5@ggc.scot.nhs.uk), ref: 19/WS/0008

Study design
Randomised clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rotator cuff tears

Interventions
The study will involve patients who are having keyhole surgery to repair their torn rotator cuff tendons. If the surgeon achieves a secure repair, patients will be randomly allocated by sealed envelope to traditional rehabilitation or accelerated rehabilitation.

Traditional rehabilitation will require use of a sling for 4-6 weeks, and those in the accelerated group will be asked to wear it for comfort, for up to 1 week. Over the following 12 months, the researchers shall assess patients' outcomes using standard outcome scores (e.g. Oxford Shoulder Score), measure their range of movement, and also measure the electrical activity in their shoulder muscles. They shall also perform a scan of their shoulder after 6 months to determine whether the tendon has healed to see whether accelerated rehabilitation affects healing.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)

Primary functional outcome measured using Oxford Shoulder Score (OSS) at 3 months post op (at patient consultation)

Key secondary outcome(s))
1. Pain and function measured using Shoulder Pain and Disability Index (SPADI) at 6 weeks, 3 months, 6 months and 12 months
2. Quality of life measured using EQ5D-5L at 6 weeks, 3 months, 6 months and 12 months
3. Pain measured using VAS at 6 weeks, 3 months, 6 months and 12 months
4. Range of movement measured by clinical assessment with long arm goniometer at 6 weeks, 3 months, 6 months and 12 months at patient consultation
5. Integrity of the repair assessed using MRI scan at 6 months post op

Completion date
01/08/2020

Eligibility

Key inclusion criteria
All patients awaiting arthroscopic rotator cuff tear surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Non-English speaker
2. Concomitant musculoskeletal disease in ipsilateral arm
3. Unfit for surgical intervention
4. Subscapularis tear
5. Massive cuff tear
6. Intra-operatively, if the tear is found not to be repairable
7. If only a partial repair was possible
8. If the repair was under tension

Date of first enrolment
01/10/2019

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester University NHS Foundation Trust
Southmoor Road
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Other

Funder Name
British Elbow and Shoulder Society; Grant Codes: Ltr014PPG/PO. No. CPRD063001

Funder Name
NIHR Central Commissioning Facility (CCF)

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes