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A randomized controlled trial to determine whether injection before physiotherapy improves the outcome for massive rotator cuff tears and which muscles are used to replace the rotator cuff in patients with good function and known massive cuff tear

Submission date
22/12/2023

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Completed

Last Edited
22/10/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
In patients over 65 years old who have had an injury that damaged tendons in their shoulder, we usually treat them with a course of physiotherapy. Some recover well but around half of these people can struggle to improve. We wanted to see if giving these patients an injection helped these patients recover, and also to look at their muscle activation patterns. This was done by recording muscle activation during tasks before and after their course of physiotherapy. Much work is done on those with chronic tears. We wanted to work with those with acute tears as we thought they might be more responsive.

Who can participate?
Patients over the age of 65 years old with acute large to massive cuff tears

What does the study involve?
Half of the participants will be given a long-lasting anti-inflammatory injection combined with a short-acting pain reliever, and half will be given just a short-acting pain reliever injection. We planned to recruit at least 15 patients for the muscle activation study.

What are the possible benefits and risks of participating?
Participants will be contributing to improving practice for the management of large rotator cuff repairs. The conclusions from this project will make suggestions for future practice and research. The injection may cause some level of pain in the short term. The injection may only give short-term relief. There are very small risks (1 in 40,000) that as a result of the steroid and/or local anaesthetic injection participants may get an infection. If this happened then they would need to see your doctor and come to hospital for the infection to be cleared. There is a very small risk of

an allergic reaction to the steroid or to the local anaesthetic (less than 1 in a 1000). This might cause swelling around the face and mouth, hands and feet, difficulty breathing or swallowing or itching of the skin. If this occurred, participants would be given a drug to compensate for the reaction. Rarely they may get temporary facial flushing (from the steroid). Rarely it is possible that there may be a very mild temporary decreased function of the limb where the injection was given (from the local anaesthetic) lasting about 24 hours. Rarely participants might have a faint (vasovagal episode) from the injection.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2013 to April 2022

Who is funding the study?
A local foxtrot grant funded some of the study

Who is the main contact?
Helen Tunnicliffe, Helen.tunnicliffe@uhl-tr.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
2013-000514-37

IRAS number
59379

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
EDGE 34451, IRAS 59379

Study information

Scientific Title
Randomized controlled trial to determine whether injection prior to physiotherapy improves the outcome for large- to massive rotator cuff tears: which muscles are used to replace the rotator cuff in patients with good function and known large -massive cuff tear, and does the location of the tear affect outcomes?

Study objectives
A randomized controlled trial was performed to investigate the following hypothesis:
1. Injection of steroids and local anesthetic improves the outcome of physiotherapy for conservative management of large/massive rotator cuff tears

Observational studies were also performed to test if:
1. Patients with a good outcome have a different maximum voluntary activation of certain muscles on EMG compared to those that do not. Those whose function improves have changed muscle activation patterns over the physiotherapy
2. Patients that have tears near the long head of the biceps tendon (rotator cable region) are less likely to achieve good outcomes with physiotherapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/10/2014, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048154; derby.rec@hra.nhs.uk), ref: 14/EM/1132

Study design
Single-centre intervention double-blinded randomized controlled trial with observational studies

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
Randomized controlled trial:
Patients with an acute cuff tear of 3 cm or more of age 65 years and who met other recruitment criteria were offered the opportunity to take part in the study to test the hypothesis of whether one injection into the subacromial space of steroid (Kennalog 40 mg) with 10 ml of 0.5% bupivacaine was more effective than just 10 ml of 0.5% bupivacaine in terms of helping the physiotherapy improve the function and decrease the pain for the patients at the end of treatment (6months or at end of treatment if sooner). Physiotherapy given was the Ainsworth regime a standard method used to treat these patients.

The patients were consented by one physiotherapist who randomly allocated the patients to one of the two arms. Randomisation was done by computer-generated random numbers which were used to create a randomisation list with stratification for the initial degree of movement of the joint and whether or not the anterior band of the supraspinatus tendon is initially intact. The randomisation within each stratum was in randomly permuted blocks of size 2, 4 or 6. Sealed envelopes were used to ensure security of randomization, these were made up by another member of the staff who had no further part in the study.

The treating physiotherapists and patients were blind to the treatment arm.

One week after their injection, patients commenced physiotherapy. This was patient-specific on timeframes but followed the deltoid regime as outlined by Ainsworth (2006). The regime aims to re-educate the anterior deltoid to compensate for the torn rotator cuff. Patients were taught the exercises by the physiotherapists at Glenfield Hospital and advised to perform them at home 3-5 times per day. Outcomes (VAS Oxford score, Constant score and range of flexion) were measured initially, at 3 months and at the end of treatment of 6 months whichever came sooner.

Observational study:
The first 15 patients were also invited to take part in an observational study to look at surface EMGs of the muscles around the shoulder initially and at the end of treatment. A wireless EMG system (Delsys Trigno, Delsys, Massachusetts, USA) was used. In the study, each muscle was recorded undertaking its maximal voluntary contraction whilst undertaking a task to isolate that muscle contraction (using a standard method). Then three tasks were undertaken (lifting the arm with and without a weight of 0.5kg and putting the and behind the back. These are standard tests used.

The tear location was correlated with the outcome at the end of the study by comparing the initial and final results for the patients with tears in different places.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Triamcinolone, bupivicaine

Primary outcome measure
Shoulder pain and function were measured using the Oxford Shoulder score prior to treatment starting and at 6 months or the end of treatment, whichever was earlier

Secondary outcome measures
1. The EMGs of the muscles around the shoulders were measured using a wireless EMG system using sensor locations according to SENIAM guidelines. Data was recorded at 2000 Hz via Delys EMG Works software. Prior to data collection of five functional tasks of five repetitions, each patient performed a maximal effort resistive task to determine their maximal voluntary contraction for each of 13 muscles examined. Measurements were taken prior to the start of treatment and at the end of treatment.
2. The location of the rotator cuff tears in the shoulder was measured by ultrasound prior to recruitment into the study.

Overall study start date
13/11/2013

Completion date
07/04/2022

Eligibility

Key inclusion criteria
1. Age over 65 years
2. Acute massive cuff tears (onset within 6 months)
3. Massive cuff tear confirmed by ultrasound scan (>3 cm)
4. Weakness of shoulder external rotation
5. Painful shoulder
6. Limited range of movement actively (<90 degrees elevation)

Participant type(s)
Patient

Age group
Senior

Lower age limit
66 Years

Sex
Both

Target number of participants
70

Total final enrolment
20

Key exclusion criteria
1. Patients under 65 years of age
2. Patients not able to exercise due to medical reasons
3. Previous surgery to the shoulder
4. Patients with poor comprehension using the mini-mental score
5. Previous physiotherapy for the same condition
6. Patients currently undergoing physiotherapy for the same condition
7. Patients with multiple joint pathologies
8. Patients unable to comply with daily exercise and weekly appointments due to other commitments
9. Passive stiffness
10. Chronic tears with no acute increase in pain
11. Needle phobia

Date of first enrolment
20/04/2015

Date of final enrolment
07/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
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LE1 5WW

Study participating centre
Loughborough Community Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.leicestershospitals.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Foxtrot Fund

Results and Publications

Publication and dissemination plan
Presented results at BESS 2022 for the EMG study as a podium presentation and as a poster at the same meeting for the effect of pain-relieving injections on the outcome of physiotherapy. Plan to submit as a paper in a high-impact peer-reviewed journal

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The data sets generated during and/or analysed during the current study will be available upon request from Helen Tunnicliffe (helen.tunnicliffe@uhl-tr.nhs.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	18/09/2014	16/01/2024	No	Yes
Protocol file	version 3	18/01/2015	16/01/2024	No	No