

Return of function and external rotation post proximal humerus fracture fixation with neutral rotation brace

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| Submission date 15/04/2014 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 13/05/2014 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 08/03/2018 | Condition category Injury, Occupational Diseases, Poisoning | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Patients who have undergone surgery for shoulder fractures have a reduced range of movement. We believe that this could be due to the traditional shoulder slings used after the operation. We believe that holding the shoulder in this position causes it to scar up and makes it difficult for the shoulder to externally rotate which reduces function. Using a neutral rotation brace will help improve patients external shoulder rotation and improve functional outcome. We would like to perform a study to compare the functional outcome with the two different slings.

Who can participate?

Patients over 18 who have shoulder fractures requiring surgery.

What does the study involve?

Participants will be randomly allocated to either having a traditional shoulder sling or a neutral rotation brace following the operation. They have to attend physiotherapy appointments at 6 weeks, 3 months, and 1 year after the operation. They will also complete some questionnaires. X-rays are taken (which is currently standard practice) at 6 weeks and 3 months to find out whether there is a fracture union (healing of the fracture) present. If there isn't a fracture union (similarly with current standard practice) patients will be followed up with x-rays until union is achieved.

What are the possible benefits and risks of participating?

The operation and post-operative treatment are standardised and no different from current practices. No increase in the number of side effects or complications is expected. Participants will help in changing current practice and improve patient functional outcome.

Where is the study run from?

Torbay District General Hospital, South Devon Healthcare NHS Foundation Trust (UK).

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

The study opened in January 2013 and is expected to continue until December 2015.

Who is funding the study?
Torbay Medical Research Fund (UK)

Who is the main contact?
Ms Veronica Conboy
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Contact information

Type(s)
Scientific

Contact name
Ms Veronica Conboy

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02073695

Secondary identifying numbers
13/01/049

Study information

Scientific Title
Return Of function And exTernal rotation post proximal humerus fracture fixation with neutral rotation brace: a randomised controlled trial

Acronym
ROTATE

Study objectives
Using a neutral rotation brace will help improve patients external shoulder rotation and improve functional outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South West - Central Bristol, 22/01/2013, ref: 12/SW/0334

Study design

Single-centre randomised interventional trial

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 contact sdhct.research@nhs.net or phone: 01803 656635 to request a patient information sheet

Health condition(s) or problem(s) studied

Trauma and orthopaedics - proximal humeral fracture

Interventions

Surgical procedure to fix proximal humeral fracture, as per standard clinical practice, same across two groups. Patients are then randomised to either having the standard polysling (as per current standard practice) or a neutral rotation brace. Questionnaires and assessments will be taken at the 6 weeks, 3 months and 1 year follow up appointments.

Intervention Type

Procedure/Surgery

Primary outcome measure

Functional outcome scores will be measured post surgery (Oxford, scores). This is a commonly used, validated outcome score used for assessment of patient outcomes.

1. Oxford Score this is a patients subjective assessment of pain and Activities of Daily Living (ADL) impairment. The Oxford Shoulder Questionnaire has been shown to correlate well with both the Constant Score and the SF36 assessment and to be sensitive to surgical intervention. The Oxford Shoulder Questionnaire accumulates to a total score with a maximum value of 60, in which four pain related questions make up 33% of this total whilst the remaining 67% is derived from eight ADL related questions. The highest scores are attributed to the worst outcomes in the Oxford Shoulder Questionnaire.

2. The Disabilities of the Arm, Shoulder and Hand (DASH) scoring system was developed to

assess the level of disability for any patient with any condition affecting the upper limb by covering domains including symptoms, physical function, social function and psychological function

Secondary outcome measures

1. Range of movement (flexion, extension, abduction, external rotation and internal rotation) this will be assessed by physiotherapists at 6 weeks, 3 months and 1 year. Measurement will be performed using a goniometer to accurately assess range of movement
2. SF12 score this is a survey form has been shown to yield summary physical and mental health outcome scores
3. Range of movement (flexion, extension, abduction and internal rotation) this will be assessed by physiotherapists at 6 weeks, 6 months and 1 year. Measurement will be performed using a goniometer to accurately assess range of movement
4. Time to union of fracture X-rays will be taken at 6 weeks and 3 months
5. Return to work post surgery this will be documented at the 1 year follow up appointment
6. Reoperations and complications this will be documented by the clinician at the various outpatient appointments.

Overall study start date

24/01/2013

Completion date

31/12/2015

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Proximal humeral fractures requiring operative intervention with extramedullary plate fixation (i.e. fractures displaced by 1cm and/or angulated by 45 degrees or more)
2. Age over 18 years of age
3. Patients able to give informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients having intraoperative findings of complete Pectoralis major rupture or if operative exposure requires complete Pectoralis major tenotomy. (These patients need to be held in internal rotation with a standard polysling to allow healing of the Pectoralis major tendon)
2. Patients under 18 years of age
3. Patients unable to give informed consent

Date of first enrolment

24/01/2013

Date of final enrolment

31/12/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Torbay District General Hospital

Torquay

United Kingdom

TQ2 7AA

Sponsor information**Organisation**

South Devon Healthcare NHS Foundation Trust (UK)

Sponsor details

R&D Manager

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TQ2 7AA

+44 (0)1803 656635

sdhct.research@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.sdhct.nhs.uk/>

ROR

<https://ror.org/05374b979>

Funder(s)

Funder type

Charity

Funder Name

Torbay Medical Research Fund (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | Protocol | 21/02/2018 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |