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

Submission date	Recruitment status	
15/04/2014	Stopped	[ ] Prospectively registered
		[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/05/2014	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/03/2018	Injury, Occupational Diseases, Poisoning	[ ] 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 isnt 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
veronica.conboy@nhs.net

Contact information

Type(s)
Scientific

Contact name
Ms Veronica Conboy

Contact details
Consultant in Trauma and Orthopaedics
Torbay District General Hospital
Lawes Bridge
Torquay
United Kingdom
TQ2 7AA
+44 (0)1803 656635
veronica.conboy@nhs.net

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 at 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
Research and Development Department
Horizon Centre
Torbay District General Hospital
Lawes Bridge
Torquay
England
United Kingdom
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