

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

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

**ClinicalTrials.gov (NCT)**  
NCT02073695

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
Torquay District General Hospital  
Torquay  
United Kingdom  
TQ2 7AA

## Sponsor information

**Organisation**  
South Devon Healthcare NHS Foundation Trust (UK)

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

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Torquay Medical Research Fund (UK)

## Results and Publications

**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?
<a href="#">Protocol article</a>	Protocol	21/02/2018		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No