

# Multi-centre randomised trial evaluating surgery for displaced fractures of the proximal humerus

<b>Submission date</b> 25/03/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/12/2021	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Fractures of the proximal humerus (the top part of the upper arm bone) are very common, particularly in older adults who have weaker bones (osteoporotic). The treatment for this type of fracture can vary, depending on how serious it is. Generally, less serious fractures are successfully treated by supporting the injured arm in a sling until the fracture mends (immobilization). If the fracture is more serious however, such as in cases where the bone has broken into two or more pieces which are out of alignment (displaced) then surgery may be a more appropriate option. Despite this little is known about whether surgical or non-surgical treatment is best for the more common types of displaced fracture. The aim of this study is to investigate the effectiveness and cost-effectiveness of surgical and non-surgical treatments for displaced fractures of proximal humerus.

### Who can participate?

Patients aged 16 or over who have fractured the top of their upper arm bone in the past 3 weeks.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group have their fracture treated surgically, either using plate fixation (where the fracture is held together by a metal plate that is screwed to the bone on either side) or joint replacement (where the damaged joint is removed and replaced with a man-made one). It is left up to the surgeon to judge which procedure is more appropriate for each individual participant. Those in the second group have their fracture treated using a sling that they wear for around 3 weeks, which is designed to hold the arm in place so that the fracture can heal. After 6, 12 and 24 months, participants in both groups complete a number of questionnaires in order to find out how well their fracture has healed and to identify any complications they have suffered.

### What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?  
James Cook University Hospital, Middlesbrough (UK)

When is the study starting and how long is it expected to run for?  
October 2008 to August 2016

Who is funding the study?  
National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?  
Professor Amar Rangan  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
HTA 06/404/53

## Study information

**Scientific Title**  
Pragmatic multi-centre randomised trial of surgical versus non-surgical treatment for proximal fracture of the humerus in adults

**Acronym**  
PROFHER

**Study objectives**  
To assess the effectiveness and cost-effectiveness of surgical versus non-surgical treatment of the majority of displaced proximal humeral fractures in adults.

Protocols can be found at [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0015/51423/PRO-06-404-53.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/51423/PRO-06-404-53.pdf)

More information can be found at <http://www.nets.nihr.ac.uk/projects/hta/0640453>

Following the completion of recruitment, it was agreed to obtain 3, 4 and 5 year data on key outcomes in order to determine whether there is any persistence or alteration of the treatment effect detected at 2 year follow-up. Secondary aims are to:

1. Obtain longer term condition specific data on shoulder function using validated instruments (OSS, EQ-5D) that will provide reference data for informing the interpretation of the findings of ProFHER and future studies of proximal humeral fractures
2. Inform future research in this area on the appropriate duration of follow-up

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

York Multi-centre Research Ethics Committee (MREC), 11/03/2008, ref: 08/H1311/12

The long term study was approved as a substantial amendment by Leeds West Research Ethics Committee on 22/09/2010.

### **Study design**

Multi-centre randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Musculoskeletal trauma of the upper limb

### **Interventions**

Interventions as of 18/10/2016:

After obtaining informed consent and key baseline information, research associates will randomly allocate patients to surgical or non-surgical treatment using an independent remote randomization service (telephone or online access) provided by the York Trials Unit (University of York). Randomization will be performed using a computer program with 1:1 allocation, stratifying by tuberosity involvement (yes or no) and using random block sizes of 4, 8, and 12. Originally after a prespecified period minimisation was to be introduced based on whether fractures involved either tuberosity and centre but was abandoned because of the small number of patients at a hospital site.

**Surgical group:** Participants allocated to surgery will receive either internal fracture fixation (e.g., with plate and screws) to preserve the humeral head or humeral head replacement (hemiarthroplasty).

**Non-surgical group:** Participants allocated to non-surgical treatment will be given a sling for the injured arm for as long as deemed necessary (3 weeks will be suggested), followed by active rehabilitation. Delivery of care and rehabilitation, which will be freely available for all patients, incorporated the following 3 set measures to ensure good standards of care within the National

Health Service: provision of an information leaflet on personal care during sling immobilization; a basic treatment protocol to guide physiotherapy; and promotion of home exercises. Rehabilitation care will be provided by physiotherapists in inpatient, outpatient, and community settings.

Participants in both groups complete a range of questionnaires and assessments at 3, 6, 12 and 24 months, and then after 3, 4 and 5 years.

Original interventions:

Participants will be randomised to one of two basic treatment interventions:

1. Surgery (fixation or joint replacement)
2. Non-surgical management (sling immobilisation)

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Oxford Shoulder Score (12-item condition-specific questionnaire providing a total score based on the person's subjective assessment of pain and activities of daily living impairment) assessed at 6, 12 and 24 months and 3, 4 and 5 years via postal questionnaire.

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

1. General health status is measured using The 12-item short form health survey (SF-12) at 6, 12 and 24 months and Euroqol (EQ-5D) at 3, 6, 12 and 24 months and 3, 4 and 5 years
2. Complications, including surgical complications (wound infection, implant failure, shoulder dislocation, septicemia) are assessed via medical record review at the end of an in-patient episode at the start of the trial and at 1 and 2 year hospital follow-up
3. Early medical complications, i.e. chest infection, confirmed myocardial infarction or stroke, treated deep vein thrombosis and pulmonary embolism are assessed via medical record review at the end of an in-patient episode at the start of the trial and other medical complications at 1 and 2 year hospital follow-up
4. Mortality rate is assessed via medical review continuously for 2 years
5. Subsequent referral for operation or substantive treatment is assessed via medical record review at 1 and 2 year hospital follow-up and then at 3, 4 and 5 year follow ups via postal questionnaire
6. NHS and societal costs are collected at 3, 6, 12 and 24 months via postal questionnaire and hospital forms: surgical form, physiotherapy form, inpatient episode form and 1 and 2 year hospital follow-up forms

## **Completion date**

12/08/2016

## **Eligibility**

### **Key inclusion criteria**

1. Aged 16 or above, male and female
2. Presenting to the participating trauma centre within 3 weeks of their injury
3. Radiologically confirmed displaced fracture of the proximal humerus involving the surgical neck
4. Surgeon would consider surgical treatment for the fracture

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Open fracture
2. Cognitive impairment that would preclude participation
3. Co-morbidities precluding surgery/ anaesthesia
4. Clear indication for surgery such as severe soft-tissue compromise requiring surgery/ emergency treatment
5. Multiple injuries: Same limb fractures, other upper limb fractures
6. Pathological fractures (other than osteoporotic)
7. Terminal illness
8. Participant not resident in trauma-centre catchment area

**Date of first enrolment**

01/10/2008

**Date of final enrolment**

28/02/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**James Cook University Hospital**

Marlon Road

Middlesbrough

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**Sponsor information**

## Organisation

Teesside University

## ROR

<https://ror.org/03z28gk75>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The current 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?
<a href="#">Results article</a>	results	01/12/2014		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Results article</a>	results	10/03/2015		Yes	No
<a href="#">Results article</a>	results	01/02/2016		Yes	No

<a href="#">Results article</a>	results	01/02/2016		Yes	No
<a href="#">Results article</a>	results	01/10/2016		Yes	No
<a href="#">Protocol article</a>	protocol	16/11/2009		Yes	No
<a href="#">Other publications</a>	commentary	01/05/2020	12/02/2020	Yes	No
<a href="#">Other publications</a>	cost-effectiveness analysis	18/08/2021	15/12/2021	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes