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

Submission date
25/03/2008

Recruitment status
No longer recruiting

Registration date
25/03/2008

Overall study status
Completed

Last Edited
15/12/2021

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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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Study website
www.york.ac.uk/healthsciences/research/trials/research/trials/profher/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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, septicaemia) 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

Overall study start date
01/10/2008

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

Age group
Adult

Sex
Both

Target number of participants
250

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
England

United Kingdom

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
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TS4 3BW

Sponsor information

Organisation
Teesside University

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Clarendon Road
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Sponsor type
University/education

Website
http://www.tees.ac.uk

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

Publication and dissemination plan
Planned publication in peer reviewed journals.

Intention to publish date
30/06/2015

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?
Protocol article	protocol	16/11/2009		Yes	No
Results article	results	01/12/2014		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	10/03/2015		Yes	No
Results article	results	01/02/2016		Yes	No
Results article	results	01/02/2016		Yes	No
Results article	results	01/10/2016		Yes	No
Other publications	commentary	01/05/2020	12/02/2020	Yes	No
Other publications	cost-effectiveness analysis	18/08/2021	15/12/2021	Yes	No