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The humeral shaft fracture trial: surgical versus non-surgical interventions for humeral shaft fractures in patients aged 18 years or older

Submission date
03/03/2020

Registration date
13/05/2020

Last Edited
16/05/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A humeral shaft fracture is a break in the long bone of the upper arm. It occurs mainly in two groups of individuals; young men and older women, as their bones are more fragile. Currently, the most common treatment for these fractures is non-operative. About 70% of cases are treated using a cast for 2 weeks and then a brace until the bone begins to heal properly – although there is a large variation in treatments between and in hospitals. The risk of complications is low and the cost is also relatively low at £1,100. The disadvantages are that the patient is immobilised for a prolonged period and the cumbersome cast can lead to significant pain and discomfort in some patients. There is also a 20% chance that the break will not heal. This then requires surgery and involves additional costs of approximately £15,500. There appears to be a worldwide trend towards treating these fractures with surgery (rather than a cast and a brace), however, there is no high-quality evidence that this is indeed a better option. Various reviews of the current evidence have recognised the need for further trials. Surgery is the more expensive route, and has a higher risk of complication e.g. infection and nerve damage. However, there is a better chance of the bone healing successfully and the patient is likely to recover more quickly allowing them to regain their independence sooner. The aim of this study is to directly compare these two methods of treating fractures of the humeral shaft. The researchers want to find out whether arm function and quality of life in patients with this fracture is better with the more conservative cast-and-brace treatment, or with surgery. They also need to compare the cost-effectiveness of both approaches. They want to produce sound evidence to establish if the drawbacks of surgery are balanced by improved results and acceptable costs.

Who can participate?
Patients aged 18 over who have a broken upper arm

What does the study involve?
Participants will be randomly allocated to receive either surgical or non-surgical (a brace) treatment for their broken upper arm. The technique of surgery used for those patients allocated to the surgery group will be chosen by the surgeon. Surgery will typically be followed

by 2 weeks in a sling. Patients treated non-surgically will have a cast applied in the Emergency Department which they will use for 2 weeks. They will then change to a brace which is usually worn for a further 8-10 weeks. Both groups will be given a structured rehabilitation programme. The researchers will collect data with regards to pain, time off work and driving, and functionality for 12 months after treatment.

What are the possible benefits and risks of participating?
Both treatments are used across the NHS currently for this type of fracture and are not new or experimental. There is a small risk of complications for participants who have the operation, such as infection or prominent metalwork as there would be with any surgery, both of which might require further treatment. The main potential risk of the brace treatment is that in about 1 of every 5 patients the bones do not heal properly. If this happens your fracture may require further treatment, which could be an operation. Both treatments are used across the NHS so there is no specific advantage for taking part in the study.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2020 to February 2025

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

Who is the main contact?
Miss Hannah Crook
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Study website
http://www.hushstudy.org

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277059

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR127817, IRAS 277059

Study information

Scientific Title
The HUmeral SHaft fracture trial (HUSH): a multi-centre prospective randomised superiority trial of surgical versus non-surgical interventions for humeral shaft fractures in patients aged 18 years or older

Acronym
HUSH

Study objectives
The aim of this pragmatic randomised controlled trial is to evaluate the clinical and cost-effectiveness of functional bracing, compared to surgical fixation for the treatment of humeral shaft fractures in patients over the age of 18.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2020, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place Nottingham NG1 6FS, UK; +44 (0)207 104 8388; cambridgecentral.rec@hra.nhs.uk), ref: 20/EE/0127

Study design
Pragmatic 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Humeral shaft fracture

Interventions
Participants will be randomised (online using RRAMP) in a 1:1 ratio stratified by centre; whether they are aged under 50 or 50 and over and whether they had a nerve injury at presentation or not, to either surgery or a brace. They will be randomised to be treated surgically or non-surgically.

The technique of surgery used for those patients allocated to the surgery group will be chosen by the surgeon. Surgery will typically be followed by 2 weeks in a sling.

Patients treated non-surgically will have a cast applied in the Emergency Department which they will use for 2 weeks. They will then change to a brace which is usually worn for a further 8-10 weeks.

Both groups will be given a structured rehabilitation programme. The trial will last for 12 months. Patients will be followed up at 6 months and 12 months after their injury. They will be asked about their quality of life, daily activities, pain, physiotherapy treatment and any complications. The researchers will also look at the resources and services they have used to determine the costs involved in both treatments.

Intervention Type
Procedure/Surgery

Primary outcome measure
Function measured using the Disabilities of Arms Shoulders and Hand (DASH) patient-reported outcome questionnaire at 12 months

Secondary outcome measures
1. Function assessed using the Disabilities of Arms Shoulders and Hand (DASH) at baseline, 8 weeks, 3 and 6 months
2. Early pain recovery assessed using pain visual analogue scale (VAS) weekly in the first 8 weeks
3. Sport and performing arts functioning assessed using the DASH sports/performing arts at baseline, 8 weeks, 3, 6 and 12 months
4. Function assessed using the patient-reported outcome measurement information system (PROMIS) upper extremity at baseline, 4 weeks, 8 weeks, 3, 6 and 12 months
5. Function assessed using the PROMIS pain interference at baseline, 4 weeks, 8 weeks, 3, 6 and 12 months
6. Quality of life measured using the EQ-5D-5L at baseline, 8 weeks, 3, 6 and 12 months
7. Complications reported at 8 weeks, 3, 6 and 12 months
8. Cost-effectiveness measured using the Work Productivity and Activity Impairment Questionnaire at 3, 6 and 12 months
9. Time off work and driving recorded in the first 8 weeks

Overall study start date
01/01/2020

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years and older with a fracture of the humeral shaft (diaphysis)
2. Fracture of the humeral diaphysis which the surgeon believes may benefit from surgical fixation. 'Diaphysis' defined as the section of bone outside 1 Muller-square of the proximal and distal ends of the humerus (Müller 1990)
3. Participant is willing and able to give informed consent for participation in the study
4. Male or female, aged 18 years or above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
334

Total final enrolment
334

Key exclusion criteria
1. The fracture is open
2. The fracture is complicated by local tumour deposits
3. The index injury occurred more than 16 days prior to recruitment
4. The patient is unable to adhere to trial procedures
5. Other upper limb injuries which may reasonably be expected to affect responses to outcome PROMs

Date of first enrolment
01/07/2020

Date of final enrolment
17/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
1st Floor
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Sponsor type
University/education

Website
https://researchsupport.admin.ox.ac.uk/ctrg

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be available prior to the completion of recruitment. The Statistical Analysis Plan and Health Economics Analysis Plan will be prepared before the final data has been collected. It is planned that each of these will be published in open-access journals.

The researchers will aim to publish the study findings as widely, speedily and efficiently as possible to allow their introduction to clinical practice and for evidence-based medicine to be used in the treatment of these patients. The research team has experience in translating research findings into clinical practice through the development of clear, evidence-based care pathways to improve patient care. A collaborative effort between health care practitioners, researchers and patients will help to make this possible. The involvement of service users (i.e. Patient Advisory Group) will ensure that project outputs are patient-orientated and relevant to the end-users.

Through the planned outputs, the study is expected to play a key role in enhancing the evidence base on efficacy, safety and cost-effectiveness of the treatment of humeral shaft fractures. Importantly, the executive summary and copy of the trial report will be sent to the National Institute of Health and Clinical Excellence (NICE) and other relevant bodies, including Clinical Commissioning Groups, so that the study findings can inform their deliberations and be translated into clinical practice nationally via the NICE non-complex fracture guidelines (https://www.nice.org.uk/guidance/ng38). The researchers will also work with the relevant National Clinical Director in the Department of Health to help ensure the findings of the trial are considered when implementing policy.

Finally, the researchers will work with the relevant Specialty Advisory Committees (SAC) to incorporate the findings into the training curriculum for clinicians who will undertake treatment humeral shaft fractures.

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date; please contact hush@ndorms.ox.ac.uk for more information.

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?
HRA research summary			28/06/2023	No	No
Protocol article		22/04/2024	03/12/2024	Yes	No
Statistical Analysis Plan	version 3.0	16/05/2025	16/05/2025	No	No