

Fix or replace enhancing distal humerus fracture outcomes

Submission date 09/09/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/06/2025	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Every year, over 4,500 adults in the UK suffer a fractured elbow. These injuries are especially common among older people. The most serious fractures involve joint damage, leading to stiffness and pain that can make everyday activities difficult. It is important that we can offer people the best chance of making a full recovery, which is why we are doing this trial. For older people with this type of fracture, there are two main treatments. Elbow arthroplasty (total or hemi replacement) involves replacing one or both sides of the elbow with an artificial metal and plastic joint. Internal fixation (repair) involves realigning and then repairing the break using metal plates and screws. Both treatments are widely used across the UK and are not experimental. However, we do not yet know which treatment is the most effective. This study aims to compare these two treatments to determine which is better.

Who can participate?

Patients aged 60 years or over who have fractured their elbow and need surgery

What does the study involve?

Participants will be randomly assigned to receive one of the two treatments: elbow arthroplasty (replacement) or internal fixation (repair). The surgery will be performed by a surgeon who is trained and experienced in the type of surgery the participant is having. Participants will receive the same check-ups and physiotherapy as any patient who has elbow surgery at each hospital. There is no difference for patients who do not take part in the trial. Participants will be asked to complete several questionnaires before their surgery and then over a 1-year period - at 6 weeks, 4 months, and 12 months after surgery. Additionally, there will be a longer-term follow-up when the trial has reached its 49th month. Questionnaires can be completed at routine clinic appointments, or they can be sent via text, email, or post, according to the participant's preference.

What are the possible benefits and risks of participating?

Taking part in the trial may not directly be of benefit, but the information collected from this trial may help to treat people who have a fracture to their elbow in the future. There is no

increased risk by participating in the trial. The NHS has treated patients with these operations for many years. Participants will face the same risks of surgery and receive the same care as patients who are having these surgeries without taking part in the trial.

Where is the study run from?

The study will be run from at least 20 different hospitals in the UK. The trial is being organised by the Nottingham University Hospitals NHS Trust (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU).

When is the study starting and how long is it expected to run for?

December 2023 to July 2029

Who is funding the study?

National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) Programme (project reference HTA: 154915) (UK)

Who is the main contact?

FOREST trial team, forest@nottingham.ac.uk

Study website

<https://nottingham.ac.uk/forest>

Contact information

Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

324227

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

23OR012, CPMS 54970

Study information

Scientific Title

A Phase III, multicentre, parallel-group, superiority RCT to compare upper limb specific function between elbow arthroplasty and fixation of the fracture using plates and screws in patients presenting with a fracture of the distal humerus

Acronym

FOREST

Study objectives

The trial will test the hypothesis that elbow arthroplasty undertaken for distal humeral fractures in older adults would: (i) result in better upper limb specific function and better health-related quality of life, and (ii) lead to less healthcare resource use and would be more cost effectiveness, compared to open reduction and internal fixation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 28/02/2025, South Central - Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford , London , E20 1JQ, United Kingdom; +44 (0)207 104 8120, +44 (0)207 104 8210, +44 (0)2071048135 ; hampshirea.rec@hra.nhs.uk), ref: 25/SC /0015

Study design

Prospective parallel two-group superiority randomized control trial, unblinded intervention, blinded for outcomes, with an internal pilot phase of 12 months

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 to request a participant information sheet

Health condition(s) or problem(s) studied

Intra-articular fracture of the distal humerus AO type B or C

Interventions

Participants will be recruited from secondary care accident and emergency (A&E) or orthopaedic clinics after a multidisciplinary team (MDT) discussion, which occurs daily in all UK centres, to assess general suitability. Eligible participants will receive a Participant Information Sheet (PIS) about the trial, typically around their first A&E presentation or via remote contact, following an elbow fracture diagnosis and eligibility confirmation. Interested participants will discuss the trial with a direct care team member and sign a consent form if willing to participate. The research team will collaborate closely with the direct care team at each centre to optimize local screening and recruitment.

Prior to randomization, participants will complete questionnaires to evaluate their current status and pre-injury elbow condition. Afterwards, they will be individually randomised to receive one of the two treatments: elbow arthroplasty (EA) or Open Reduction Internal Fixation (ORIF) in a 1:1 ratio. Dynamic randomisation will use a probabilistic minimisation algorithm to balance across arms by recruitment site, sex, diabetes, injury to the dominant limb, and fragility fracture.

Elbow arthroplasty refers to any surgical intervention involving joint replacement, where metal components are inserted into the bone to replace all or part of the elbow joint, as deemed suitable by the treating specialist. Elbow repair, also known as open reduction internal fixation (ORIF), involves surgical fixation of the fracture using plates and screws, as determined appropriate by the treating specialist.

The surgery will be performed by a trained and experienced surgeon, which may require traveling to a specialist hospital. This is common for these injuries as the surgery is performed by highly specialised surgeons. Surgery should be completed within 14 days of injury. During surgery, participants will receive their allocated procedure. However, the surgeon may decide to perform a different procedure during the operation if it is deemed to be in the participant's best

interest. This is unlikely, as pre-operative x-rays will have already indicated that either procedure was suitable, but it remains a possibility.

After surgery, the participant will receive the same check-ups and physiotherapy as any patient who has had elbow surgery at that hospital. Follow-up will continue for 1 year post-surgery through questionnaires at 6 weeks, 4 months, 12 months, and at an additional 49-month timepoint (for those reaching this point). These questionnaires can be completed during routine clinic follow-ups or sent via text, email, or post according to participant preference, taking no longer than 20 minutes each time.

Intervention Type

Procedure/Surgery

Primary outcome measure

Upper limb specific function measured using the Disabilities of the Arm, Shoulder and Hand (DASH) score at 4 months post-surgery

Secondary outcome measures

1. Upper limb specific function measured using the DASH at baseline (for pre-injury function), 6 weeks and 12 months post-surgery and at the 49-month whole study timepoint
2. Upper limb specific function measured using the Oxford Elbow Score (OES) at baseline (for pre-surgery function), 6 weeks, 4- and 12 months post-surgery
3. Elbow pain measured using the Patient Rated Elbow Evaluation form (PREE) at baseline, 6 weeks, 4- and 12 months post-surgery
4. Health-related quality of life (QoL) measured using the EQ-5D-5L at baseline (for pre-injury QoL and pre-surgery QoL), 6-weeks, 4- and 12 months post-surgery
5. Healthcare resource use and comparative cost-effectiveness measured using a purposely designed patient self-reported questionnaire completed prior to point of discharge from hospital, at 6 weeks, 4- and 12-months post-surgery

Overall study start date

01/12/2023

Completion date

31/07/2029

Eligibility

Key inclusion criteria

1. Aged ≥ 60 years
2. Intra-articular distal humerus fracture
3. Suitable for surgical treatment with either elbow arthroplasty (EA) or ORIF
4. Injury to anticipated day of surgery ≤ 21 days

Participant type(s)

Patient

Age group

Adult

Lower age limit

60 Years

Sex

Both

Target number of participants

320

Key exclusion criteria

1. Open fracture
2. Pathological fracture
3. Patient not suitable for surgery
4. Patient unable to adhere to trial protocol/procedures
5. Multiple fractures in the same arm precluding one treatment option
6. Any other injury that, in the opinion of the treating clinician, is likely to significantly alter arm function/ outcomes

Date of first enrolment

27/05/2025

Date of final enrolment

01/02/2028

Locations**Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus

Nottingham University Hospital

Derby Road

Nottingham

United Kingdom

NG7 2UH

Study participating centre

Royal Infirmary of Edinburgh at Little France

51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre**Wrightington, Wigan and Leigh NHS Foundation Trust**

Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust

Sponsor details

Research and Innovation
Queen's Medical Centre
Derby Road
Nottingham
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United Kingdom
NG7 2UH
+44 (0)1159249924
ResearchSponsor@nuh.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.nuh.nhs.uk/>

ROR

<https://ror.org/05y3qh794>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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

The results of this trial will be submitted for publication in a peer-reviewed journal(s). Trial publications and conference abstracts will be submitted to the National Institute for Health Research (NIHR) for approval prior to submission to the event organisers or the editors. All publications will acknowledge the support of the NIHR in funding this trial.

A lay summary of the results will be sent to all participants at the end of the trial (who consented) and will also be made available via the trial website.

Intention to publish date

31/07/2030

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. Identifiable data will only be accessed by authorised members of the research team after the participants have given consent for their data to be accessed. Access will be limited to the trial staff and investigators and relevant regulatory authorities. The research database will be kept separate from participant contact information. Computer-held data will be held securely and password-protected on the trial database. The trial database to be used is REDCap. It is a validated secure web-based platform which allows for data tracking via date-stamped audit logs, it adheres to GCP guidance.

Confidentiality of all participant information will be maintained throughout the trial. Each participant will be assigned a unique trial identification number, allocated at randomisation. This

number will be used for data collection forms, other trial forms and the trial database. Study documents will also use the participant's initials (of first and last names separated by a hyphen or a middle name initial when available).

Data will be held on secure servers. These servers are located within the University of Nottingham data centres, which are managed and monitored regularly. Security is both physical (secure limited role-based access) and electronic (behind firewalls, access via user accounts (username and password) on encrypted connections, restricted access – e.g. site staff only have access to their site patient data, and by user type/role). All access and data transactions will be logged in a full audit trail.

Paper consent forms will be kept in a locked office at each recruiting centre, separate from trial data. An electronic copy of the consent forms will be uploaded to the secure, password protected University of Nottingham hosted database; this will be detailed within the patient information and consent documentation. Data obtained via the electronic consent method will be stored in the secure, password protected University of Nottingham hosted database; this will be detailed within the patient information and consent documentation.

Personal data will not be shared outside of the trial team. Trial data will be collected and stored securely with the knowledge and consent of the participant as outlined in the participant information sheet and informed consent form. Access to identifiable information will be restricted to those responsible for the follow-up of participants and those performing data linkages. In the database, in which identifiable data (including contact details and NHS number) is stored, field-level encryption will be used to prevent unauthorised persons from accessing the personal data.

Personal contact details will be available to the Nottingham Clinical Trials Unit (NCTU) so they can contact participants during the trial and send questionnaires. Names and telephone numbers may be shared with Esendex, the text messaging provider and their subprocessors, in order to send text message reminders about the trial and trial questionnaires whilst participating in the trial. Once participation has ended Esendex will no longer contact participants but will retain the data for two years or until the end of the study (whichever occurs first). Participants who withdraw from the trial and no longer wish to receive any trial material will have their details deleted from Esendex.

The data generated by the trial will be analysed by staff at the Nottingham Clinical Trials Unit (NCTU), specifically the Medical Statistics team and the Health Economics team at NCTU. No data will be transferred outside the UK.

IPD sharing plan summary

Stored in non-publicly available repository