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Fix or replace enhancing distal humerus fracture outcomes

Submission date	Recruitment status
09/09/2024	Recruiting
Registration date	**Overall study status**
19/03/2025	Ongoing
Last Edited	**Condition category**
16/03/2026	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
324227

Protocol serial number
23OR012

Central Portfolio Management System (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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s))

Current secondary outcomes as of 16/03/2026:
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) pain sub-scale 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 staff-completed case report forms and a purposely designed patient self-reported questionnaire completed prior to point of discharge from hospital and at 6 weeks, 4 and 12 months post-surgery
6. Patient recovery of function measured using discharge destination, days in usual residence, days to return to driving, days absent from paid work and use of health services prior to point of discharge from hospital and at 6 weeks, 4 and 12 months post-surgery

Previous secondary outcomes:
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, and 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

Completion date

31/07/2029

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 16/03/2026:
1. Aged ≥ 60 years
2. Intra-articular distal humerus fracture (AO type B or C)
3. Suitable for surgical treatment with either EA or ORIF
4. Injury to anticipated day of surgery ≤28 days

Current key inclusion criteria as of 16/08/2025:
1. Aged ≥ 60 years
2. Intra-articular distal humerus fracture (AO type B or C)
3. Suitable for surgical treatment with either EA or ORIF
4. Injury to the anticipated day of surgery ≤21 days

Previous 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 the anticipated day of surgery ≤21 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 14/08/2025:
1. Open fracture
2. Metastatic 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
7. Previous participation in the FOREST clinical trial

Previous 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
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Royal Infirmary of Edinburgh at Little France
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
Scotland
EH16 4SA

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes