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Comparing surgical fixation and conservative management using a cast in wrist fractures in people aged 65 years and older

Submission date
02/12/2021

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Ongoing

Last Edited
09/11/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Fractures of the radius bone in the lower arm near to the wrist are the most common fracture, accounting for 16% of all fractures. They are commonest in elderly patients after falls. At the Royal Infirmary of Edinburgh alone, we see over 1000 of these fractures each year. When the bony fragments displace (move) out of position the current best treatment is surgical fixation. In our centre, this is most commonly achieved by fixing the bone fragments with a metal plate and screws inserted from the volar (front) side of the wrist. While this makes for better bone position, its effect on function in elderly patients is unclear. There is no general agreement for about the best way to manage wrist fractures in elderly people and practice varies widely. Some previous research showed no clear benefit of surgery over a cast in terms of patient-reported outcomes (the results that are considered most important to patients) in the elderly. The current randomised controlled trials (RCTs) in the scientific literature have limitations and demonstrate mixed results, with some showing that surgical fixation results in better outcomes whilst others suggest that there is no difference. Recent literature reviews combining the results of many research studies found that, although the surgery group had slightly improved function, it might not be worth the risks involved in surgery. We want to carry out an RCT to compare functional outcomes of non-surgical management and surgical fixation of displaced distal radius fractures (a type of wrist fracture) in patients aged 65 years and older. If it is shown that a cast is just as good as surgery, this could save thousands of unnecessary operations each year both in the UK and abroad.

Who can participate?
All patients aged 65 years and older presenting to the Edinburgh Orthopaedic Trauma Service with the correct type of broken wrist (distal radius fracture) will be invited to participate in the study. We intend to recruit 184 patients.

What does the study involve?
Patients who take part in this study will receive treatment either with a cast or with an operation. Which technique they receive is entirely decided by random allocation and will be decided immediately on agreeing to take part. All other aspects of care will be identical to the

care received out with the study.
Patients can take as long as they need to decide whether to take part, but they are only eligible to take part for the first 3 weeks after their fracture and we usually aim not to delay any treatment. One of the orthopaedic doctors who is familiar with the study and the treatments will discuss the study with the patient, answer any questions and go through a study consent form with them, asking them to sign this if they agree to take part. Patients will then be randomly allocated to either surgery or cast treatment. Those patients for surgery will be listed for surgery on our routine trauma list. This is usually done as a day case within a few days but can take up to 1 to 2 weeks (in other words patients can go home and come back for surgery as long as they will be safe at home in the meantime). COVID-19 has changed the way that patients are cared for in many ways. Depending on the guidelines at the time, patients may need to self-isolate and then undergo a test for COVID-19 before they come in for an operation. Patients for cast management will have follow-up arranged in the outpatient clinic to ensure their cast is in adequate condition.
After treatment, we intend to follow up all participants for 1 year. This involves three routine visits to the Royal Infirmary of Edinburgh at 2 weeks, 6 weeks and 12 weeks, with questionnaires via the post or over the phone at 6 months and 1 year following surgery. At follow-up clinic visits, which are required whether or not patients are part of the study, patients will be reviewed by a doctor from the orthopaedic team. They will be asked some simple questions about their progress, as well as take a short series of wrist and hand movement and strength tests. Patients will be asked to complete questionnaires regarding their level of wrist function and will be asked to undergo 2 wrist x-rays. The whole process should take approximately 60 minutes at each visit. Patients may be seen by a member of the physiotherapy team if they are felt to require this. The questionnaires that will be sent at 6 months and 1 year after injury are part of the study and not part of standard clinical care.
We will also review patient records to see whether you need any further wrist operations within 2 years. This will not require any further outpatient appointments.

What are the possible risks and benefits of participating?
There are no direct benefits of taking part. However, the information we get from this study should help improve the treatment of people who suffer your type of injury in the future.
There are risks involved with each of the treatment options. Overall, we do not currently know which option is better – hence the need for this study.
Conservative treatment in a cast: In the short term, this is very simple and has very few complications associated with it. It is possible that patient's longer-term outcome will be as good as with surgery, but this may not be the case. It may be that patients end up with stiffness and/or pain in the wrist. In the rare occasion this happens, then there is the option for an operation later to re-break the bone and straighten it. This operation is usually successful, although most patients do complain of some degree of ongoing stiffness and discomfort afterwards.
Surgical management with an operation: The risks of this treatment include bleeding, infection, nerve injury, prominent metal that requires removal, ongoing pain/ stiffness, along with rare complications associated with anaesthesia and surgery.
Patients who take part in this study will have x-rays (and potentially x-ray guided surgery) of the wrist. Up to one of these x-rays will be additional to those that they would have if they did not take part. These procedures use ionising radiation to form images of the body and provide the doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. Taking part in this study will add only a very small chance of this happening.

Where is the study run from?
The Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
October 2019 to July 2027

Who is funding the study?
The Scottish Orthopaedic Research Trust Into Trauma (SORT-IT) (UK) and the Orthopaedic Trauma Association (OTA) (USA)

Who is the main contact?
1. Mr Andrew Duckworth (scientific contact), andrew.duckworth@ed.ac.uk
2. Miss Katrina Bell (public contact), katrina.bell@nhslothian.scot.nhs.uk

Contact information

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Public

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Integrated Research Application System (IRAS)
283764

Study information

Scientific Title
Elderly - Fixation Of the Radius: Radiological and Clinical Evaluation (eFORRCE): a prospective randomised superiority trial of surgical versus conservative management for unstable fractures of the distal radius in patients aged 65 and older.

Acronym
eFORRCE

Study objectives
The Patient-Rated Wrist Evaluation (PRWE) score with surgical fixation is superior to that with conservative management at 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/09/2021, Scotland B Research Ethics Committee (2nd Floor Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5680; manx.neill@nhslothian.scot.nhs.uk), ref: 21/SS/0061

Primary study design
Interventional

Study design
Single-centre interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unstable fractures of the distal radius in patients aged 65 years and older

Interventions
Surgical patients will be treated routinely with standard volar plate techniques as per routine trauma care. Following surgery, the post-operative assessment and course will be as per normal protocol for patients who are not in this study. Physiotherapy will be arranged as required at the discretion of the treating surgeon.

Non-operatively managed patients will receive 6 weeks in cast and then be referred to physiotherapy at the discretion of the treating surgeon. The cast will be in the form of a below-

elbow Plaster of Paris Colles backslab (a type of plaster cast used to treat distal radius fractures) for the first week following injury. This will be completed with synthetic cast material after one week and then changed to a circumferential below-elbow Colles synthetic cast at 2 weeks post-injury until 6weeks post-injury.

Participants will be randomised to receive surgical or conservative management on a 1:1 ratio. An independent statistician employed through the University of Edinburgh research methodology department will produce a computer-generated randomisation schedule using a block randomisation with a random block size. Randomisation will be stratified based on the fracture AO classification to ensure as far as possible that there are equal numbers of type A and C fractures in each treatment arm. Classification of fracture type will be carried out by one of the consultants involved in the study. In 2010-2011, there were 505 distal radius fractures in patients aged ≥65 years, of which 351 were type A, 111 were type C and the remaining fractures were of a type that would not be eligible for study inclusion. It is therefore expected to be 76% type A and 24% type C. Two separate randomisation lists will be produced, one for type A fractures and a second for type C fractures. A member of staff independent from the trial will use this list to create opaque sequentially sealed envelopes for each list containing a participant identification number and the treatment allocation. To aid identification and ensure that the next randomisation envelope is taken from the appropriate list, the fracture type (A or C) will be stated on the front of the envelopes with differently coloured stickers for each arm.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Wrist pain and disability assessed using the Patient-Rated Wrist Evaluation (PRWE) at 1 year (52 weeks) post-injury

Key secondary outcome(s)
1. Wrist pain and disability assessed using the Patient-Rated Wrist Evaluation (PRWE) at 12 and 26 weeks
2. Health-related quality of life measured using EuroQol 3 Dimensions (3L) Score (EQ-5D-3L) at 12 weeks, 26 weeks and 52 weeks
3. Physical function of the upper limb measured using the Quick Disabilities of the Arm Shoulder and Hand (QuickDASH) score at 12 weeks, 26 weeks and 52 weeks
4. Pain assessed by VAS pain score at 2 weeks, 6 weeks, 12 weeks, 26 weeks and 52 weeks
5. Healthcare resource use, and comparative cost-effectiveness at 1 year (52 weeks) using data collected from patient interviews and questionnaire responses and appropriate statistical and economic analysis methods
6. Complication rate obtained by patient questionnaire responses and reviewing patient notes at 1 year (52 weeks)
7. Grip strength assessed using a dynamometer at 12 weeks
8. Wrist range of motion assessed using a goniometer at 12 weeks
9. Radiographic parameters (including radial inclination, radial height, ulnar variance, carpal malalignment, dorsal tilt, intra-articular step and intra-articular gap) assessed using X-ray imaging at 2 weeks, 6 weeks, 12 weeks, 26 weeks and 52 weeks

Completion date
27/07/2027

Eligibility

Key inclusion criteria
1. Aged ≥65 years
2. Dorsally angulated fractures of the distal radius
3. The treating surgeon believes the patient is suitable for surgical fixation
4. Operation date within 3 weeks of fracture
5. Closed or Gustilo-Anderson grade I injury

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
65

Key exclusion criteria
1. Patients unable to give informed consent
2. Patients medically unfit to undergo surgery
3. Volar displaced fractures
4. Partial articular and isolated radial styloid fractures
5. Associated fractures to the upper limb and/or pre-existing pathology adversely affecting function
6. Associated ligamentous injury, dislocation or subluxation of the wrist
7. Open fractures of Gustilo-Anderson grade II or higher
8. Persisting neurovascular deficit requiring operative intervention
9. Off-ended/severely displaced fractures post attempted reduction that are deemed to require surgery by the treating surgeon
10. Non-residents who will be unable to attend for local follow-up
11. Patients unable to comply with follow-up, including English-language patient-reported outcome measures, either on the telephone or by post

Date of first enrolment
07/02/2022

Date of final enrolment
27/07/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Royal Infirmary of Edinburgh
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Other

Funder Name
Orthopaedic Trauma Association

Alternative Name(s)
Orthopaedic Trauma Association, Incorporated, Orthopedic Trauma Association Inc, The Orthopaedic Trauma Association, OTA

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United States of America

Funder Name
Scottish Orthopaedic Research Trust Into Trauma (SORT-IT)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study (fully anonymised) will be available upon request after the publication of the study results from Miss Katrina Bell (katrina.bell@nhslothian.scot.nhs.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/10/2024	24/10/2024	Yes	No