Distal Radius Acute Fracture Trial 3 - a randomised study to compare a plaster cast to a removable splint for patients with a broken wrist

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
26/01/2023		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
27/01/2023	Ongoing	☐ Results			
Last Edited	Condition category Musculoskeletal Diseases	Individual participant data			
14/02/2024		Record updated in last year			

Plain English summary of protocol

Background and study aims

There are over 100,000 fractures of the wrist (distal radius) in the UK each year; 6% of all women will have sustained such a fracture by the age of 80 and 9% by the age of 90. Following a fracture of the distal radius, if the bone fragments have remained in their normal alignment, the fracture can be treated with a support for the injured wrist, which will provide pain relief and protects from further damage as the fracture heals. Over three quarters of all distal radius fractures in adults fall into this category and outcomes are generally good.

For those patients whose fracture remains aligned, usual care is to provide the patient with a temporary 'backslab' plaster cast in the emergency department. The patient is then referred to the orthopaedic fracture clinic where the backslab is converted to a full fibre-glass cast. The patient has to return to the fracture clinic 4-6 weeks later to have their cast removed.

Recently, there has been some evidence that a removable wrist splint may provide the patient with the same support as a cast while their fracture heals. A splint can be removed by the patient themselves thereby avoiding additional visits to the hospital. This could be more convenient for patients and save money for the NHS.

This study will compare wrist function and pain in patients with a fracture of the distal radius treated with usual care in a cast with standard follow-up versus a removable wrist splint with discharge from the emergency department.

Who can participate?

Patients aged 16 years and older with an acute fracture of the distal radius who, in the opinion of the treating clinician, do not require a manipulation of the fracture. Patients presenting to the research team more than two weeks after they sustain their injury; those who have an open fracture; or patients who would be unable to follow trial procedures will be excluded.

What does the study involve?

1894 adult patients with a fracture of their distal radius will be invited to take part from hospitals across the UK. Half of those that agree to take part will be treated in a cast and half in a removable splint. All of the patients will be given the same information and advice about their injury and their recovery. Which treatment a person gets will be decided by a computer to ensure a fair comparison. Everyone has an equal chance of getting either treatment. During the first two weeks, we will monitor the patients' pain and after three, six and twelve months everyone will receive a questionnaire. The questionnaires will ask about what activities they are able to do, their quality of life, any problems they might have and any costs that have been incurred because of the injury.

What are the possible benefits and risks of participating?

Both treatments in this study are used across the NHS at the moment. They are not new or experimental. We do not know whether there is a difference in recovery for patients who get a cast or a splint. This is why we are doing the research. If patients join in, they will help us make treatment for future patients with similar injuries better. This study will also give us information about the best use of resources within the NHS. There are some standard risks of having a plaster cast or splint, such as rubbing on the skin, feelings of pins and needles, or numbness (temporary loss of feeling) and stiffness. These risks are the same for any patient having these treatments. They are not affected by whether patients join this research study or not.

Where is the study run from?

The Oxford Trauma and Emergency Care research team are responsible for the day-to-day running of the study as part of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskeletal Sciences (NDORMS) and the Oxford Clinical Trials Research Unit (OCTRU).

When is the study starting and how long is it expected to run for? May 2022 to April 2026

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact? Trial Manager, Heather Barnes, draft3-casp@ndorms.ox.ac.uk

Contact information

Type(s)

Scientific

Contact name

Miss Heather Barnes

Contact details

Oxford Trauma and Emergency Care NDORMS Trauma Unit, Kadoorie Centre John Radcliffe Hospital Oxford United Kingdom

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

314712

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 54355, NIHR134681, IRAS 314712

Study information

Scientific Title

Distal Radius Acute Fracture Trial 3 – Cast versus Splint (DRAFT3-CASP): a randomised non-inferiority trial comparing clinical and cost-effectiveness of a standard care cast versus removable splint for adults with a distal radius fracture that does not require manipulation

Acronym

DRAFT3-CASP

Study objectives

Treatment with a removable splint with discharge from ED is no less clinically and cost effective than a cast with follow-up as per usual care for the treatment of acute distal radius fractures that do not require manipulation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/01/2023 South West – Frenchay Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 1048106; frenchay.rec@hra.nhs.uk), ref: 22/SW/0177

Study design

Interventional randomized non-inferiority trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fractures in the distal radius that do not need manipulation

Interventions

This trial is a pragmatic, randomised non-inferiority clinical trial with participant follow-up to 12 months post-randomisation.

Participants will be randomised to either Plaster Cast or Removable Splint for treatment of their distal radius fracture; the randomisation will be on a 1:1 basis, stratified by centre and age (<50 vs ≥50 years).

In a 6 month internal pilot phase, we expect to open 6 sites after which the Data Safety Management Committee (DSMC) will advise the Trial Steering Committee (TSC) on continuation of the trial. The TSC will evaluate this information and make a decision based on this and other information that they require for a decision.

In the study as a whole, a total of 1894 participants will be recruited in a minimum of 36 Emergency departments within the UK. A member of the research team at each site will screen patients for eligibility and when this is confirmed by a clinician, a study trained member of the team will approach the patient to explain the study and gain informed consent. Participants will complete questionnaires at baseline, and will complete follow-up questionnaires on days 1,3,5,7,10 and 14 during the first 2 weeks. They will then complete further follow-up questionnaires at week 7, month 3, month 6 and month 12 after randomisation.

Data will be collected via the clinical trial IT system REDCap, hosted by the University of Oxford, UK. Baseline demographic data will be entered directly by the site staff during the initial visit, and all baseline questionnaire data will be entered directly by the participant. Participants will then be contacted for follow-up using email and/or SMS text message prompts and invited to complete questionnaires through an online link. Telephone and postal follow-up will be conducted for those who require it. Follow-up will be conducted centrally by the trial team.

A process evaluation will be conducted with up to 20 interviews with participants and up to 20 clinicians will be asked to participate in either a focus group or individual interview. For participants who wish to be supported during their interview, a relative/friend/informal carer (up to 10) may also be interviewed. The interviews will focus on participants' experience of injury, treatment and acceptability of the splint with immediate discharge or no planned follow up, recovery, and participation in the trial.

Intervention Type

Procedure/Surgery

Primary outcome(s)

To quantify and draw inferences on observed differences in function between treatment groups, as measured by the Patient Rated Wrist Evaluation (PRWE) at 3 months post-randomisation.

Key secondary outcome(s))

- 1. To quantify and draw inferences on observed differences in pain related to the wrist fracture between treatment groups, as measured by the Visual Analogue Scale (VAS) pain score, on days 1, 3, 5, 7, 10 and 14 post-randomisation.
- 2. To quantify and draw inferences on observed differences in medium-term pain and function between treatment groups, as measured by the PRWE at Baseline, 7 weeks and 6 and 12 months post-randomisation and measured by the PROMIS Upper Limb Physical Function Score at

Baseline, and 3, 6 and 12 months post-randomisation.

- 3. To quantify and draw inferences on observed differences in health-related quality of life between treatment groups, as measured by EQ-5D-5L at Baseline, 7 days and 3, 6, and 12 months post-randomisation.
- 4. To quantify and draw inferences on observed difference in the complication rate between treatment groups, including the need for subsequent manipulation or surgical fixation using the patient reported complications form at day 14, week 7 and 3, 6 and 12 months postrandomisation.
- 5. To investigate the healthcare and broader resource implications for both treatment groups using the Health Resource Questionnaire at 3, 6 and 12 months post-randomisation.
- 6. To quantify the comparative cost effectiveness of the trial treatments using the Health Research Questionnaire at 3, 6 and 12 months post-randomisation.

Completion date

30/04/2026

Eligibility

Key inclusion criteria

- 1. Participant is willing and able to give informed consent for participation in the study.
- 2. Aged 16 years or above.
- 3. Presenting with a fracture of the distal radius which, in the opinion of the treating clinician, does not require a manipulation of the fracture.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 years

Sex

All

Key exclusion criteria

- 1. Present to research team more than 2 weeks post-injury
- 2. The fracture is open (Gustilo and Anderson > 1)
- 3. They are unable to adhere to trial procedures, e.g. patients with permanent cognitive impairment, or other concomitant severe injuries e.g. head injury.

Date of first enrolment

20/02/2023

Date of final enrolment

01/11/2024

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre Addenbrookes

Addenbrookes Hospital Hills Road Cambridge United Kingdom CB2 0QQ

Study participating centre Aintree University Hospital

Lower Lane Liverpool United Kingdom L9 7AL

Study participating centre Royal Liverpool University Hospital

Mount Vernon St Liverpool United Kingdom L7 8YE

Study participating centre Royal Hampshire County Hospital

Romsey Road Winchester United Kingdom SO22 5DG

Study participating centre Glan Clwd Hospital Ysbyty Glan Clwydd

Bodelwyddan Rhyl United Kingdom LL18 5UJ

Study participating centre James Cook University Hospital

Marton Road Middlesbrough United Kingdom TS4 3BW

Study participating centre John Radcliffe Hospital

Headley Way Oxford United Kingdom OX3 9DU

Study participating centre Kettering General Hospital

Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Kings Mill Hospital

Mansfield Road Sutton-in-ashfield United Kingdom NG17 4JL

Study participating centre Musgrove Park Hospital (taunton)

Musgrove Park Hospital Taunton United Kingdom TA1 5DA

Study participating centre Royal Berkshire Hospital

Royal Berkshire Hospital London Road Reading United Kingdom RG1 5AN

Study participating centre Royal Derby Hospital (nuh)

Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Royal Devon and Exeter Hospital

Royal Devon & Exeter Hospital Barrack Road Exeter United Kingdom EX2 5DW

Study participating centre Salford Royal Hospital

Stott Lane Eccles Salford United Kingdom M6 8HD

Study participating centre South Tyneside District Hospital

South Tyneside District Hospit Harton Lane South Shields United Kingdom NE34 OPL

Study participating centre

Southmead Hospital

Southmead Way Bristol United Kingdom BS10 5NB

Study participating centre St. Georges Hospital

Blackshaw Road London United Kingdom SW17 0QT

Study participating centre University Hospital of North Tees

Hardwick Road Stockton-on-tees United Kingdom TS19 8PE

Study participating centre Wrexham Maelor Hospital

Croesnewydd Road Wrexham Technology Park Wrexham United Kingdom LL13 7TD

Study participating centre Yeovil District Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre Frimley Park Hospital

Frimley Park Scanning Centre Portsmouth Road Frimley Camberley

United Kingdom GU16 7UJ

Study participating centre Wexham Park Hospital

Wexham Street Wexham Slough United Kingdom SL2 4HL

Study participating centre The Royal Glamorgan Hospital

Ynysmaerdy Pontyclun United Kingdom CF72 8XR

Study participating centre Airedale General

Airedale General Hospital Skipton Road, Steeton Keighley United Kingdom BD20 6TD

Study participating centre Derriford Hospital

Derriford Road Plymouth United Kingdom PL6 8DH

Study participating centre Princess Alexandra Hospital

Hamstel Road Harlow United Kingdom CM20 1QX

Study participating centre Queens Hospital

Queens Road Croydon United Kingdom CR9 2PQ

Study participating centre Sandwell General Hospital

Lyndon West Bromwich United Kingdom B71 4HJ

Study participating centre Norfolk & Norwich University Hospital

Colney Lane Colney Norwich United Kingdom NR4 7UY

Study participating centre North West London Hospitals NHS Trust

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Sponsor information

Organisation

University of Oxford

ROR

https://ror.org/052gg0110

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	06/01/2023	26/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes