

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

<b>Submission date</b> 26/01/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/02/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:draft3-casp@ndorms.ox.ac.uk)

### **Study website**

<https://draft3-study.digitrial.com>

## **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  
OX3 9DU  
+44 1865223113  
draft3-casp@ndorms.ox.ac.uk

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

314712

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home, Hospital, Internet/virtual

**Study type(s)**

Treatment

**Participant information sheet**

<https://draft3-study.digitrial.com>

**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 measure**

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.

### **Secondary outcome measures**

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 post-randomisation.
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.

### **Overall study start date**

01/05/2022

### **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

### **Age group**

Adult

### **Lower age limit**

16 Years

### **Sex**

Both

**Target number of participants**

1894

**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**

England

United Kingdom

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 0PL

**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

### Sponsor details

University Offices  
Oxford  
England  
United Kingdom  
OX1 2JD

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ctrq@admin.ox.ac.uk

### Sponsor type

University/education

### Website

<http://www.ox.ac.uk/>

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Government

### Funder Name

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

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

30/04/2027

## 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?
<a href="#">Participant information sheet</a>	version 2.0	06/01/2023	26/01/2023	No	Yes
<a href="#">HRA research summary</a>			28/06/2023	No	No