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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
26/01/2023

Recruitment status
No longer recruiting

Registration date
27/01/2023

Overall study status
Ongoing

Last Edited
14/02/2024

Condition category
Musculoskeletal Diseases

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

Study website
https://draft3-study.digitrial.com

Contact information

Type(s)
Scientific

Contact name
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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

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University of Oxford

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Oxford
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United Kingdom
OX1 2JD
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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?
Participant information sheet	version 2.0	06/01/2023	26/01/2023	No	Yes
HRA research summary			28/06/2023	No	No