ISRCTN10931294 https://doi.org/10.1186/ISRCTN10931294

When children up to 11 years old break the bones in their wrists, do they need surgery to perfectly realign the bones, or will nature 'self-correct' the bones as they heal without restricting the use of the arm?

Submission date
24/02/2020

Recruitment status
No longer recruiting

Registration date
27/02/2020

Overall study status
Ongoing

Last Edited
20/04/2026

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
The most common part of the body for a child to break is their wrist. Most need a simple plaster cast, but some undergo surgery to reset the bones before they go into a cast. These operations are really common, but doctors are unsure whether they are really necessary in younger children. In children up to 11 years old, even when the bones break and move totally out of place, there is evidence to suggest that the wrist will heal well and will grow back to normal over a few months. Parents and children want to know if surgery is really necessary, or whether a plaster cast with natural healing will be as good.

Who can participate?
All children aged 4-10 years old (inclusive) who have a severely broken wrist

What does the study involve?
Participants are randomly allocated either to be treated with a cast, allowing the arm to straighten naturally, or to be treated with a procedure to straighten the arm. Parents will be asked to complete some questions with their child about their pain, activities and feelings. These questions will be asked when if they decide to take part, and on four further occasions over the next 12 months. To assess the longer-term effects of the injury, the same questions will also be asked at the two and three year anniversary of the injury. Parents and children may be invited to take part in a sub-study exploring the experience of their child’s injury, its impact on their daily life and the parent’s experience of being asked to participate this study. A link to the questions will be sent to a mobile phone or email address and should take no more than 10 minutes to complete.

What are the possible benefits and risks of participating?
Both treatment options are currently being used to treat this type of injury and each carries a

different set of risks. There are no additional risks to your child from taking part in the study. Risks of non-surgical treatment: the injured arm may not look the same as the other arm while it heals; healing may take longer and; in rare cases, if the arm does not grow straight an operation may be required. Risks of a procedure or operation to put the bones back into the right position: sometimes the doctors may have to make a cut in the arm to insert plates or wires to hold the bones in position, which would need to be removed at a later stage. The bone may still move out of place and in those who have an operation an infection may sometimes occur. Children in both groups are at risk of irritation related to the cast, pressure areas and a condition related to muscle swelling called compartment syndrome.

Where is the study run from?
University of Oxford, based at the John Radcliffe Hospital (UK)

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Daniel Perry
CRAFFT@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Daniel Perry

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https://orcid.org/0000-0001-8420-8252

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Additional identifiers

Integrated Research Application System (IRAS)
264593

Central Portfolio Management System (CPMS)

44878

Study information

Scientific Title
CRAFFT – Children's Radius - Acute Fracture Fixation Trial: a multi-centre prospective randomised non-inferiority trial of surgical reduction versus non-surgical casting for displaced distal radius fractures in children

Acronym
CRAFFT

Study objectives
Treatment with non-surgical casting is non-inferior to surgical reduction for the treatment of severely displaced fractures of the distal radius in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2020, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048106; nrescommittee.westmidlands-blackcountry@nhs.net), REC ref: 20/WM/0054

Study design
Randomized; Interventional; Design type: Treatment, Surgery, Other

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Radius acute fracture

Interventions
This trial will compare two approaches to treat displaced distal radius fractures in children aged 4-10 years old inclusive. Participants are randomised to either:

Non-surgical casting:
This technique involves the application of a plaster cast to hold the bone fragments in the optimal possible position using analgesia, but without giving medication to deliberately alter the conscious level of the child. This may be the initial plaster cast used to stabilise the fracture, or the plaster cast may be changed by the clinician to maximise patient comfort and fracture stability. Although the principles of applying a plaster cast are inherent in the technique, in this pragmatic trial the type of casting material, extent of the cast and the details of the technique will be left to the discretion of the treating clinician as per their usual technique. A record will be made of the cast details and any cast changes. The usual practice is for the plaster cast to be used for 4-6 weeks.

A procedure or operation:
A procedure or operation will be performed (with or without fixation). The bones will be realigned under general anaesthesia or sedation altering the conscious state of the child. The method used to hold the bones in position will be at the discretion of the clinician; i.e. plaster cast alone, plaster cast and wires, plaster cast and plate. A record will be made of the operative details, the cast details and any cast changes. Following surgery, the usual practice is for the arm to be immobilised in a cast for 4-6 weeks. Specific details on the techniques and materials used in theatre will be collected for each participant.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Functional recovery assessed using the Patient Report Outcomes Measurement System (PROMIS Bank v2.0) Upper Extremity Score for Children Computer Adaptive Test (CAT) at 3 months post-treatment

Key secondary outcome(s))
1. Upper extremity function is measured using the PROMIS Upper Extremity Score during the first year post-treatment
2. Pain is measured using the Wong-Baker FACES Pain Scale (an ordinal assessment using a series of six facial-expressions to illustrate the degree of pain intensity) during the first year post-treatment
3. Health-related quality of life is measured using EQ-5D-Y (Youth version) between during the first year post-treatment
4. Complication rate, including re-fracture, the need for further operative fixation and the absence of radiographic remodelling, measured through a qualitative assessment of radiographs by a surgeon consensus group up to 1-year post-treatment
5. Cost-effectiveness of the treatments to the NHS and the broader economy is measured by collecting resource use information, including inpatient/outpatient hospital attendance, other NHS or private services and out of pocket expenses up to 1-year post-treatment
6. Parental satisfaction with the cosmetic appearance of the arm measured using a visual analogue score (VAS) during the first year post-treatment
7. Patient satisfaction with care measured using an ordinal satisfaction score during the first year post-treatment
8. An assessment of impact of injury, treatment and recovery on parent and child experience of daily life and the outcomes that are important to them will be measured through qualitative interview during the first year post-treatment
9. The barriers and facilitators to trial recruitment from parent/child and staff perspectives will be measured through qualitative interview during the first year post-treatment

Long-term outcomes to be reported separately:
10. Longer-term pain, function and complications will be measured using the methods described above (i.e. Wong-Baker, PROMIS-UE and complications record) annually up until 3 years post-treatment

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. Male and female children aged 4 to 10 years inclusive
2. Parents/guardians willing and able to give informed consent for their child's participation in the study
3. There is radiographic evidence of a severely displaced wrist fracture at or adjacent to the physis (Salter-Harris II or a metaphyseal fracture); with or without a corresponding ulna fracture
4. The treating clinician believes that they may benefit from surgical reduction with or without fixation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
10 years

Sex
All

Total final enrolment
750

Key exclusion criteria
1. The injury is more than 7 days old
2. The injury is part of a more complex wrist fracture (i.e. open or fracture extending into the joint)
3. There are other fractured bones elsewhere in the body, in addition to the affected wrist injury
4. There is evidence that the patient and/or parent would be unable to adhere to trial procedures or complete follow-up, such as insufficient English language comprehension, developmental delay or a developmental abnormality or no access by parents to mobile data /internet

Date of first enrolment
11/08/2020

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Alder Hey Children’s Hospital
Eaton Road
Liverpool
England
L12 2AP

Study participating centre
Basingstoke & North Hampshire Hospital & Royal Hampshire County Hospital
-
Basingstoke
England
RG24 9NA

Study participating centre
Birmingham Children's Hospital
Steelhouse Ln
Birmingham
England
B4 6NH

Study participating centre
Bristol Royal Hospital for Children
Upper Maudlin St
Bristol
England
BS2 8BJ

Study participating centre
Epsom and St Helier University Hospitals
Dorking Rd
Epsom
England
KT18 7EG

Study participating centre
Hull Royal Infirmary
Anlaby Rd
Hull
England
HU3 2JZ

Study participating centre
John Radcliffe Hospital & Horton Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Leeds General Infirmary
Great George St
Leeds
England
LS1 3EX

Study participating centre
Leighton Hospital
Middlewich Rd
Crewe
England
CW1 4QJ

Study participating centre
Macclesfield District General Hospital
Victoria Rd

Macclesfield
England
SK10 3BL

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

Study participating centre
Musgrove Park Hospital
Parkfield Dr
Taunton
England
TA1 5DA

Study participating centre
Nottingham University Hospital (Queen's Medical Centre)
Derby Rd
Nottingham
England
NG7 2UH

Study participating centre
Ormskirk District General Hospital
Dicconson Way
Wigan Rd
Ormskirk
England
L39 2AZ

Study participating centre
Royal Aberdeen Children’s Hospital
-
Aberdeen
Scotland
AB25 2ZG

Study participating centre
Royal Alexandra Children’s Hospital
Eastern Road
Brighton
England
BN2 5BE

Study participating centre
Royal Berkshire Hospital
London Rd
Reading
England
RG1 5AN

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LQ

Study participating centre
Royal London Hospital
-
Whitechapel
England
E1 1BB

Study participating centre
Royal Manchester Children's Hospital
Oxford Rd
Manchester
England
M13 9WL

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent

England
ST4 6QG

Study participating centre
Royal Victoria Infirmary
-
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
Sheffield Children's Hospital
Western Bank
Sheffield
England
S10 2TH

Study participating centre
St George's Hospital
Blackshaw Rd
London
England
SW17 0QT

Study participating centre
University Hospital Coventry
Clifford Bridge Rd
Coventry
England
CV2 2DX

Study participating centre
University Hospital Southampton
Tremona Rd
Southampton
England
SO16 6YD

Study participating centre

Barnsley Hospital
Gawber Road
Barnsley
England
S75 2EP

Study participating centre
Basildon University Hospital
Nethermayne
Basildon
England
SS16 5NL

Study participating centre
Doncaster Royal Infirmary and Bassetlaw Hospital
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Surrey
England
GU16 7U

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Kettering General Hospital
Rothwell Rd
Kettering
Northants

England
NN16 8UZ

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton In Ashfield
England
NG17 4JL

Study participating centre
New Cross Hospital
-
Wolverhampton
England
WV10 0QP

Study participating centre
Pinderfields Hospital
Rowan house
Aberford Road
Wakefield
England
WF1 4DG

Study participating centre
Princess Alexandra Hospital NHS Trust
Hamstel Rd
Harlow
Essex
England
CM20 1QX

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
England
BB2 3HH

Study participating centre
Stepping Hill Hospital
Poplar Grove
Stockport
England
SK2 7JE

Study participating centre
Torbay Hospital
Lawes Bridge
Torquay
England
TA2 7AA

Study participating centre
Victoria Hospital Kirkcaldy & Queen Margaret Hospital
Whitefield Road
Dunfermline
Fife
Scotland
KY12 0SU

Study participating centre
Warrington Hospital
Lovely Lane
Warrington
England
WA5 1QG

Study participating centre
Wexham Park Hospital
Wexham Street
Slough
England
SL2 4HL

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford

England
BD9 6RJ

Study participating centre
Southend Hospital
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
England
BA21 4AT

Study participating centre
Gwynedd Hospital (ga)
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
Wales
LL57 2PW

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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 are/will be available upon request from the chief investigator (Daniel.perry@ndorms.ox.ac.uk). Applications will be considered by the Oxford Trauma and Emergency Care senior management group, with the intention to release anonymised data to academic groups for the purpose of high-quality individual patient data meta-analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/04/2026	20/04/2026	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article		08/04/2026	13/04/2026	Yes	No
Other files	Health economics analysis plan version 2.0	06/10/2021	22/08/2025	No	No
Statistical Analysis Plan	version 2.0	05/08/2025	22/08/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes