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	[X] Prospectively registered		
		☐ Protocol		
Registration date 27/02/2020	Overall study status Ongoing	[X] Statistical analysis plan		
		☐ Results		
Last Edited 22/08/2025	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data		
		[X] Record updated in last year		

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

ORCID ID

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

Contact details

University of Oxford, NDORMS Kadoorie Centre Level 3, John Radcliffe Hospital Oxford United Kingdom OX3 9DU +44 (0)1865228929 Daniel.Perry@ndorms.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 44878, IRAS 264593

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

Participant type(s)

Patient

fixation

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 United Kingdom CB2 0QQ

Study participating centre Alder Hey Children's Hospital

Eaton Road Liverpool United Kingdom L12 2AP

Study participating centre Basingstoke & North Hampshire Hospital & Royal Hampshire County Hospital

Basingstoke United Kingdom RG24 9NA

Study participating centre Birmingham Children's Hospital

Steelhouse Ln Birmingham United Kingdom B4 6NH

Study participating centre Bristol Royal Hospital for Children

Upper Maudlin St Bristol United Kingdom BS2 8BJ

Study participating centre Epsom and St Helier University Hospitals

Dorking Rd Epsom United Kingdom KT18 7EG

Study participating centre Hull Royal Infirmary

Anlaby Rd Hull United Kingdom HU3 2JZ

Study participating centre John Radcliffe Hospital & Horton Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Leeds General Infirmary

Great George St Leeds United Kingdom LS1 3EX

Study participating centre

Leighton Hospital

Middlewich Rd Crewe United Kingdom CW1 4QJ

Study participating centre Macclesfield District General Hospital

Victoria Rd Macclesfield United Kingdom SK10 3BL

Study participating centre Milton Keynes University Hospital

Standing Way Eaglestone Milton Keynes United Kingdom MK6 5LD

Study participating centre Musgrove Park Hospital

Parkfield Dr Taunton United Kingdom TA1 5DA

Study participating centre Nottingham University Hospital (Queen's Medical Centre)

Derby Rd Nottingham United Kingdom NG7 2UH

Study participating centre Ormskirk District General Hospital

Dicconson Way Wigan Rd Ormskirk United Kingdom L39 2AZ

Study participating centre Royal Aberdeen Children's Hospital

Aberdeen United Kingdom AB25 2ZG

Study participating centre Royal Alexandra Children's Hospital

Eastern Road Brighton United Kingdom BN2 5BE

Study participating centre Royal Berkshire Hospital

London Rd Reading United Kingdom RG1 5AN

Study participating centre Royal Cornwall Hospital

Treliske Truro United Kingdom TR1 3LQ

Study participating centre Royal London Hospital

Whitechapel United Kingdom E1 1BB

Study participating centre

Royal Manchester Children's Hospital

Oxford Rd Manchester United Kingdom M13 9WL

Study participating centre Royal Stoke University Hospital

Newcastle Road Stoke-on-Trent United Kingdom ST4 6QG

Study participating centre Royal Victoria Infirmary

Newcastle upon Tyne United Kingdom NE1 4LP

Study participating centre Sheffield Children's Hospital

Western Bank Sheffield United Kingdom S10 2TH

Study participating centre St George's Hospital

Blackshaw Rd London United Kingdom SW17 0QT

Study participating centre University Hospital Coventry

Clifford Bridge Rd Coventry United Kingdom CV2 2DX

Study participating centre University Hospital Southampton

Tremona Rd Southampton United Kingdom SO16 6YD

Study participating centre Barnsley Hospital

Gawber Road Barnsley United Kingdom S75 2EP

Study participating centre Basildon University Hospital

Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre Doncaster Royal Infirmary and Bassetlaw Hospital

Doncaster Royal Infirmary Armthorpe Road Doncaster United Kingdom DN2 5LT

Study participating centre Frimley Park Hospital

Portsmouth Road Frimley Surrey United Kingdom GU16 7U

Study participating centre Gloucester Royal Hospital

Great Western Road

Gloucester United Kingdom GL1 3NN

Study participating centre Kettering General Hospital

Rothwell Rd Kettering Northants United Kingdom NN16 8UZ

Study participating centre Kings Mill Hospital

Mansfield Road Sutton In Ashfield United Kingdom NG17 4JL

Study participating centre New Cross Hospital

Wolverhampton United Kingdom WV10 0QP

Study participating centre Pinderfields Hospital

Rowan house Aberford Road Wakefield United Kingdom WF1 4DG

Study participating centre Princess Alexandra Hospital NHS Trust

Hamstel Rd Harlow Essex United Kingdom CM20 1QX

Study participating centre Royal Blackburn Hospital

Haslingden Road Blackburn United Kingdom BB2 3HH

Study participating centre Stepping Hill Hospital

Poplar Grove Stockport United Kingdom SK2 7JE

Study participating centre Torbay Hospital

Lawes Bridge Torquay United Kingdom TA2 7AA

Study participating centre Victoria Hospital Kirkcaldy & Queen Margaret Hospital

Whitefield Road Dunfermline Fife United Kingdom KY12 0SU

Study participating centre Warrington Hospital

Lovely Lane Warrington United Kingdom WA5 1QG

Study participating centre Wexham Park Hospital

Wexham Street

Slough United Kingdom SL2 4HL

Study participating centre Bradford Royal Infirmary

Duckworth Lane Bradford United Kingdom BD9 6RJ

Study participating centre Southend Hospital

Prittlewell Chase Westcliff-on-sea United Kingdom SSO 0RY

Study participating centre Yeovil District Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre Gwynedd Hospital (ga)

Ysbyty Gwynedd Penrhosgarnedd Bangor United Kingdom LL57 2PW

Study participating centre Wythenshawe Hospital

Southmoor Road Wythenshawe Manchester United Kingdom M23 9LT

Study participating centre University Hospitals Plymouth NHS Trust

Derriford Hospital Derriford Road Derriford Plymouth United Kingdom 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 data-sharing plans for the current study are unknown and will be made 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
Other files	Health Economics Analysis Plan version 2.0	06/10/2021	22/08/2025	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	version 2.0	05/08/2025	22/08/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes