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
19/07/2024

Condition category
Injury, Occupational Diseases, Poisoning

[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
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

Study website
http://www.CRAFFTstudy.org

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
264593

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2019

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

Age group
Child

Lower age limit
4 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
Planned Sample Size: 750; UK Sample Size: 750

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
England

Scotland

United Kingdom

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
Queen Alexandra Hospital
Southwick Hill Rd
Hampshire
United Kingdom
PO6 3LY

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
Sunderland Royal Hospital
Kayll Rd
Sunderland
United Kingdom
SR4 7TP

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
SS0 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

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office, 1st floor
Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
+44 (0)1865 289886
ctrg@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
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

Publication and dissemination plan
The protocol will be available prior to the completion of recruitment. The Statistical Analysis Plan and Health Economics Analysis Plan will be prepared before the final data has been collected. It is planned that each of these will be published in open-access journals.

Planned publication will be via high-impact peer-reviewed journals, and will be disseminated on social media using infographics and cartoons around one year after the trial has ended.

Intention to publish date
31/03/2028

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