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The forearm fracture recovery in children evaluation study

Submission date	Recruitment status
12/10/2018	No longer recruiting
Registration date	**Overall study status**
12/10/2018	Completed
Last Edited	**Condition category**
01/08/2022	Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Torus (buckle) fractures of the wrist are the most common fractures in children. They result from injury to growing bones and account for 500,000 UK emergency attendances annually. Torus fractures have a very low risk of complications and universally heal well. There is considerable variation in the treatment of torus fractures, from the use of a removable rigid splint, to plaster cast immobilisation, to more flexible splints or soft bandages. The key differences are the degree of immobilisation provided and the follow-up required. Non-removable rigid casts are no longer recommended for the treatment of these injuries. Removable splints immobilise the wrist and may provide the best pain relief. Soft bandaging restricts movement the least and may encourage early function, but concern remains about pain and the potential for complications, despite evidence to the contrary. The National Institute for Health and Care Excellence (NICE) concluded that bandaging was probably the best treatment approach due to the convenience, adequate pain control and the ability to promote early function, though asked whether any treatment is really necessary. NICE also recommended that no follow-up of these injuries is necessary because they are almost always complication free and they universally heal well. However, there is variable follow-up at different hospitals. The aim of this study is to assess the effectiveness of the optional use of soft bandage and immediate discharge, compared to rigid splint immobilisation.

Who can participate?
Children aged 4 to 15 with a torus fracture of the wrist

What does the study involve?
Each participant is randomly allocated to either a soft bandage and immediate discharge, or rigid splint immobilisation and follow-up as per current practice at the treating centre. Participants are asked to record their pain and complete questionnaires to assess their ability to use their arm and their quality of life. This information is collected by a smartphone/email link to an electronic questionnaire at various intervals over a 6-week period.

What are the possible benefits and risks of participating?
The results may show the best way to treat these injuries in the future. The treatments involved in this study are of no additional risk to the participant.

Where is the study run from?
John Radcliffe Hospital (UK)
The study will be recruiting from a minimum of 15 centres treating children's fractures across the UK

When is the study starting and how long is it expected to run for?
July 2018 to August 2020

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Mrs Louise Spoors
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Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 17/23/02; Sponsor PID: 13849

Study information

Scientific Title
A multi-centre prospective randomized equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilisation for torus fractures of the distal radius in children

Acronym
FORCE

Study objectives
FORCE is an equivalence trial. The aim of this pragmatic RCT is to evaluate the clinical and cost-effectiveness of soft bandage immobilisation and immediate discharge, compared to rigid splint immobilisation and follow-up as per the protocol of the treating centre, for the treatment of torus fractures of the distal radius in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2018, West Midlands – Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Email: NRESCommittee.WestMidlands-Solihull@nhs.net), ref: 18/WM/0324

Study design
Multi-centre prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Torus (buckle) fractures of the distal radius in children

Interventions
Each patient will be randomly allocated (1:1) with a randomisation sequence stratified by centre and age group (4-7 years and ≥8 years):
1. Soft bandage immobilisation and immediate discharge
2. Rigid splint immobilisation and follow-up as per the protocol of the treating centre

Participants are asked to record their pain and complete questionnaires to assess their ability to use their arm and their quality of life. This information will be collected via a smartphone/email link to an electronic questionnaire at various intervals over a 6 week period.

Intervention Type

Device

Primary outcome(s)
Pain measured using the Wong-Baker FACES Pain Rating Scale at three days post randomisation

Key secondary outcome(s))
1. Pain measured using the Wong-Baker FACES Pain Rating Scale at 1 day, 1, 3 and 6 weeks post randomisation
2. Use of regular analgesia assessed by questionnaire/survey via text at 1, 3 and 7 days post randomisation
3. Functional recovery measured using the Patient Report Outcomes Measurement System (PROMIS) Upper Extremity Limb Score for Children Computer Adaptive Test at 3 days, 1, 3 and 6 weeks post randomisation
4. Health-related quality of life measured using EQ-5DY at 3 days, 7 days, 3 and 6 weeks post randomisation
5. Number of days of school absence assessed by questionnaire/survey via text up to 3 and 6 weeks post randomisation
6. Complications, including the need for further hospital attendance, assessed by questionnaire /survey via text at 3 and 6 weeks post-randomisation
7. Resource use and comparative cost effectiveness assessed by questionnaire/survey via text at 3 and 6 weeks post randomisation

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Radiographic evidence of a torus fracture of the distal radius whereby there is a cortical deformation within the distal third of the radius but no break in the cortex. These may be associated with an ipsilateral fracture to the ulna (the ulna fracture may be buckle, greenstick or otherwise)
2. Aged 4 to 15 years old inclusive
3. Randomisation must occur at the site able to definitively treat the injury (i.e. a centre able to take the decision regarding the definitive treatment approach, which will typically be the emergency department)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit

15 years

Sex
All

Total final enrolment
965

Key exclusion criteria
1. The injury is more than 36 hours old
2. The treating clinician judges that there is a cortical disruption of the radius on radiographs (i.e. a greenstick fracture)
3. They have sustained an additional fracture at the time of the index fracture (with the exception of ipsilateral ulna fractures)
4. There is evidence that the patient and/or parent/guardian 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 a telephone

Date of first enrolment
01/11/2018

Date of final enrolment
12/07/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Alder Hey Children's Hospital
Eaton Road
Liverpool
United Kingdom
L12 2AP

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

Study participating centre
Bristol Royal Hospital for Children
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

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

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Horton General Hospital
Oxford Road
Banbury
United Kingdom
OX16 9AL

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

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

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Royal London Hospital
Whitechapel
United Kingdom
E1 1BB

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 Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
New Cross Hospital
Wednesfield Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
University Hospital Southampton
University Hospital Southampton NHS Foundation Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal Berkshire Hospital
Royal Berkshire NHS Foundation Trust
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Wexham Park Hospital
Frimley Health NHS Foundation Trust
Wexham Park
Slough
United Kingdom
SL2 4HL

Study participating centre
Royal Devon & Exeter Hospitals
Royal Devon and Exeter NHS Foundation Trust
Barrack Rd
Exeter
United Kingdom
EX2 5DW

Study participating centre
Evelina London Children's Hospital
Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Rd
Lambeth
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

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 analysed during the current study may be made available upon request. All data requests should be submitted to Daniel Perry (daniel.perry@ndorms.ox.ac.uk). Access to anonymised data may be granted following review.
Data will be freely available after the Monograph is published, and for 5 years thereafter, for anyone to look up and to use for whatever purpose. Individual patient data will be made available for IPD met analysis only, subject to agreement.
All data will be anonymised and any free text responses from participants removed to ensure this. All participants have consented to the study and there are no ethical or legal restrictions. Anonymised patient-level data will be shared in a format appropriate to the nature of the data-sharing project.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/07/2022	06/07/2022	Yes	No
Results article		01/07/2022	01/08/2022	Yes	No
Protocol article	protocol	01/06/2020	05/08/2020	Yes	No
Basic results		06/07/2022	06/07/2022	No	No
HRA research summary			28/06/2023	No	No
Other publications	Does digital, multimedia information increase recruitment and retention in a children's wrist fracture treatment trial, and what do people think of it? A randomised controlled Study Within A Trial (SWAT)	13/07/2022	14/07/2022	Yes	No
Participant information			06/07	No	Yes

sheet			/2022		
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V3.0	13/11/2019	30/12/2019	No	No
Statistical Analysis Plan	Statistical analysis plan	01/06/2020	05/08/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes