ISRCTN13955395 https://doi.org/10.1186/ISRCTN13955395

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
FORCE@ndorms.ox.ac.uk

Study website
http://www.forcestudy.org

Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://force-dissemination.digitrial.com/app/uploads/2022/06/FORCE-PI-Leaflet-Dev-v6.pdf

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 measure
Pain measured using the Wong-Baker FACES Pain Rating Scale at three days post randomisation

Secondary outcome measures
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

Overall study start date
02/07/2018

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

Age group
Child

Lower age limit
4 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
696

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
England

United Kingdom

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

Sponsor details
Joint Research Office
1st floor, Boundary Brook House
Churchill Drive
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Oxford
England
United Kingdom
OX3 7LQ

Sponsor type
University/education

Website
http://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/force

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

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 on the NIHR website.

Dissemination of the results will be via traditional and novel methods:
1. Conference: Traditional conference dissemination will focus on presentations to include the key professional stakeholders (emergency medicine doctors, orthopaedic surgeons, emergency nurse practitioners and trainees in emergency medicine and orthopaedics)
2. Publications: Key outputs will be published in high-impact journals with publicity sought in other professional journals (e.g. Pulse, HSJ, Nursing Times). The trialists will ensure that plain English summaries are published alongside the full paper, along with links to other digital media on the trial website to explain the trial result in an accessible format – i.e. an explainer video and infographic. Given the frequency of the injury, this is also likely to be of interest to international press outlets
3. Policy Makers: The trialists will ensure the development of links with key organisations such as NICE, NHS Information Centre, NHS England and Quality Observatories to contribute to and capitalise on their networks. Most importantly the outputs will directly contribute to the NICE non-complex fracture guidelines, and will be directly relevant to the widely publicised Choosing Widely Campaign
4. Public Dissemination: To ensure a broad campaign the trialists will target a range of social media outlets (e.g. twitter and blogs such as MumsNet) with the explainer video and infographic. They will seek to engage the NHS Dissemination centre, and seek to publish 'digital story' as part of the 'NIHR Signal'. Finally, they will produce a Wikipedia page for this injury (currently absent) and update this with the trial result

Added 27/03/2019:
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.

Added 30/12/2019:
The protocol (not peer reviewed) has been uploaded as an additional file.

Intention to publish date
01/12/2021

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?
Protocol file	version V3.0	13/11/2019	30/12/2019	No	No
Protocol article	protocol	01/06/2020	05/08/2020	Yes	No
Statistical Analysis Plan	Statistical analysis plan	01/06/2020	05/08/2020	No	No
Basic results		06/07/2022	06/07/2022	No	No
Participant information sheet			06/07/2022	No	Yes
Results article		02/07/2022	06/07/2022	Yes	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
Results article		01/07/2022	01/08/2022	Yes	No
HRA research summary			28/06/2023	No	No