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Management of ankle fractures in children

Submission date	Recruitment status	[X] Prospectively registered
13/11/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/11/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
01/11/2023	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is common for children to sustain fractures (breaks) to their bones, and current estimates are that 1 in 3 children will sustain a break during childhood. Despite the common nature of these injuries, there are few research studies to guide the best way to treat them. One of the most common injuries in children is a broken ankle, and the majority of these do not need an operation. There are a range of different ways to treat these so-called 'stable' injuries including the use of a supportive bandage (tubigrip), brace, or plaster cast. Each has its own advantages and disadvantages and a recent survey suggested that there is a range of different treatments offered to the same injury in different hospitals.

Who can participate?
The study is looking for children aged 5-15 who break a bone in their ankle.

What does the study involve?
X-rays will be reviewed by the doctors who will decide if the child is eligible for the trial. The study will involve being allocated to one of three common treatments for this injury - a removable bandage, a removable splint or a walking cast. The child will be prescribed this for 2 weeks and will be allowed to walk using crutches. Follow up will be through online questionnaires sent to families to track progress and with a 2-week patient diary that needs to be returned to the study team.

What are the possible benefits and risks of participating?
The researchers cannot promise the study will help the participants but the information from this study may help children with similar injuries recover with the best possible outcomes. There are no anticipated disadvantages in participating in this study. All of the treatments are safe and commonly used to treat this fracture in the UK. Previous studies have suggested that the risk of pressure injuries (skin irritation or blisters) may be slightly higher with the boot. This risk will be reduced by providing a padded sock to wear with this device. It is possible to develop a heat-related injury with the cast which is why only trained staff will apply and remove this device.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2020 to November 2023

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

Who is the main contact?
Jessica Nightingale
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Study website
https://www.nottinghamorthopaedics.co.uk

Contact information

Type(s)
Scientific

Contact name
Miss Jess Nightingale

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277534

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46531, IRAS 277534

Study information

Scientific Title

Management of ANkle fractures in CHildren: the feasibility Of a Randomised controlled trial (ANCHOR)

Acronym
ANCHOR

Study objectives
Is it feasible to conduct a randomised controlled trial to compare cast, removable splint and supportive bandage for low-risk ankle fractures in children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2020, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8285; derby.rec@hra.nhs.uk), ref: 20 /EM/0189.

Study design
Interventional randomized controlled trial

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
Injuries to the knee and lower leg

Interventions
A feasibility multi-centre parallel group trial with 1:1:1 allocation of patients to removable splint treatment with a brace or bandage or below knee cast. The trial will collect outcome data at 6 and 12 weeks with nested qualitative interviews to inform future trial design.

Children presenting with an acute ankle injury will be assessed in the Emergency Department and a provisional diagnosis identified. Emergency department treatment will be at the discretion of the treating clinician. Children are reviewed at a specialist fracture clinic within 72 of presentation in line with the British Orthopaedic Association’s BOAST 7 recommendations. Children who are managed in virtual fracture clinics or in emergency department fracture clinics may be recruited directly from the emergency department.

The parents will decide if their child is eligible to take part in the trial in conjunction with their surgeon and child and will be referred to the research team. Screening logs will be maintained throughout the trial to assess the main reasons for patient exclusion as well as number of patients unwilling to take part. For parents and children in whom English is not their first language trial materials will be available translated on request. However, patients will only be invited to participate if they are able to complete the outcome measures in English, as there are no validated translations of the candidate measures.

The primary outcomes will be collected using a electronic form at recruitment, at 2 and 6 week follow up and at 12 weeks.

Intervention Type
Other

Primary outcome measure
Feasibility outcome measures:
1. Recruitment rates compared to site screening logs as the number of eligible participants who are randomized in the study
2. Retention rates, drop out and crossovers as a proportion of recruited patients who complete the study regime
3. Adherence to treatments measured using a patient diary for 14 days of treatment
4. Trial experience and qualitative feedback from participants collected through structured interviews with a sample of participants at 12-24 weeks

Secondary outcome measures
1. Physical function measured by ASK-P, PROMIS Mobility at 6 and 12 weeks
2. Quality of life measured by EQ-5D-Y and PedsQL4.0 at 6 and 12 weeks
3. Global rating of change score at 6 and 12 weeks
4. Daily pain scores measured using a patient diary for 14 days of treatment
5. Re-injury rates measured using a self-reported questionnaire at 6 and 12 weeks
6. Complications measured using a self-reported questionnaire at 6 and 12 weeks

Overall study start date
01/11/2020

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Aged 5-15 years inclusive
2. Proven low-risk ankle fracture on x-ray: minimally displaced or undisplaced fibular fracture
3. A clinical undisplaced fracture which fulfils the Ottawa criteria:
3.1. A history of trauma
3.2. Tenderness at the posterior edge of the lateral malleolus
3.3. Unable to weight bear for more than 4 steps
3.4. No alternative cause of pain identified on x-ray

Participant type(s)

Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Planned Sample Size: 156; UK Sample Size: 156

Total final enrolment
103

Key exclusion criteria
1. Additional injuries
2. Injury is more than 7 days old at recruitment
3. Current medical condition that prevents the use of any of the treatments (e.g. dermatitis, vasculitis, congenital foot or ankle deformities)
4. In conjunction with their parents are unable to complete the outcome measures chosen in English

Date of first enrolment
10/12/2020

Date of final enrolment
10/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospital
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Alder Hey Children’s Hosptial
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Trust Headquarters
Queens Medical Centre
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Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200580

Results and Publications

Publication and dissemination plan
Study results will be presented at national and international meetings and disseminated via peer reviewed journals. Participants will be provided with a plain English summary of results and a statement will be placed on the group's website.

Intention to publish date
10/06/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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
Protocol file	version 3.2	28/02/2022	01/11/2023	No	No