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A study evaluating whether immobilisation or no immobilisation affects pain scores in toddlers fractures

Submission date
18/12/2024

Recruitment status
Not yet recruiting

Registration date
23/06/2025

Overall study status
Ongoing

Last Edited
23/06/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Toddler's fractures are breaks in the tibia (shin bone) that often occur as a result of a minor trip, twist or fall. Children present with pain, limping or an inability to put their weight through their leg. The break is in the lower part of the bone towards the ankle, and usually heals well. In younger children, the bones have a thick covering that protects the bone and allows for quick healing. Managing toddlers' fractures differs greatly depending on which hospital you go to. Some doctors will treat in a cast and allow the child to walk on the leg. Others use just a walking boot, a bandage or no form of immobilisation. There are pros and cons to each treatment. This study will look at whether treating without a cast is an appropriate alternative in terms of pain, convenience for the child and family, and value for money to the NHS.

Who can participate?
The study will include children aged 9 months up to and including their 4th birthday who have had, or are clinically suspected to have, a toddler's fracture. Children cannot participate if they have multiple injuries, suspected non-accidental injuries, or certain bone or limb conditions.

What does the study involve?
Participants will be randomly split into two groups. One group will be treated with a cast or walking boot for their fracture. One group will be managed without a cast. Parents will be asked to complete questionnaires at 72 hours, 3 days, and 28 days after randomisation, which will include questions on their child's pain, their satisfaction with the treatment, and how quickly they started moving around.

What are the possible benefits and risks of participating?
Taking part in the study will help us to get a better understanding of the most effective treatment for toddlers' fractures. The study aims to minimise the burden on parents by using simple questionnaires for a short duration. Participants are not required to visit the hospital again as part of the study.

Either of these methods of treatment (immobilisation or no immobilisation) may be offered in usual practice outside of the study, and both may have their own risks and benefits. Treatment of toddlers' fractures via immobilisation of the leg is most common, but this can be associated with other complications. This could include pressure sores, skin breakdown, stiffness of the ankle and knee joint, as well as pain from the cast rubbing. The use of immobilisation impacts activities of daily life for children and their families. It can also lead to delayed recovery from the injury by limiting movement and causing temporary stiffness and weakness of the limb. Toddler's fractures are stable injuries and should not be displaced if not immobilised. However, there are concerns that without immobilisation, there is a risk of the broken bone displacing, that more pain is felt during recovery, and a risk of worsening of the injury. The inability to participate in normal activities, such as attendance at nursery, may also be affected.

Where is the study run from?
The study is sponsored by Sheffield Children's Hospital and is coordinated by the University of Sheffield. The study will be conducted across a minimum of 20 National Health Service (NHS) Trusts in the UK, including children's hospitals, tertiary units, and district general hospitals.

When is the study starting and how long is it expected to run for?
The study starts in January 2025 and aims to start recruiting in September 2025 for a recruitment duration of 18 months. The project ends in October 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme.

Who is the main contact?
Study Manager: Katie Ridsdale, k.ridsdale@sheffield.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR165783

Study information

Scientific Title
Treatment of Toddlers Fractures: Observation Or Immobilisation (TOTs)

Acronym
TOTs

Study objectives
The hypothesis of this trial is that immobilisation is non-inferior to immobilisation in regard to pain, in toddlers with aged 9 months to 3 years with fractures.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/06/2025, West of Scotland Research Ethics Service 5 (Level 2 Administration Building, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH, United Kingdom; +44 (0)141 314 0213; ggc.wosrec5@nhs.scot), ref: 25/WS/0066

Study design
Multicenter prospective parallel-group individually randomized (1:1) pragmatic non-blinded controlled non-inferiority trial with 6-week follow-up and health economic analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Toddler's fractures - non-displaced spiral fractures of the tibia

Interventions
Participants will be randomised 1:1, using an online system provided by the Sheffield CTRU, to non-immobilisation management or immobilisation. Patients randomised to 'immobilisation' should receive an above/below knee cast, which should be applied in the emergency department, plaster room or fracture clinic, as either a Plaster of Paris backslab or full cast, a synthetic soft cast with a supporting underlayer of rigid material as a backslab, or a synthetic full cast. The cast will include an underlayer of wool with optional use of stockinette and adhesive felt for pressure areas. The type of material used will be pragmatic and depend on the acute hospital standard care for cast application.

Patients randomised to 'no immobilisation' will not receive immobilisation. They can be offered a soft crepe bandage 3-6 inches in diameter without any underlayer, applied circumferentially to

include the foot and leg extending no further than the mid-thigh, and not restricting ankle or knee movement. It is personal choice if participants/parents would like to accept this or not.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain is measured using the Face, Legs, Activity, Cry, Consolability (FLACC) behavioural pain assessment scale (or revised FLACC for children with cognitive impairment) at baseline, 72 hours, day 7 (primary) and day 28

Secondary outcome measures
Current secondary outcome measures as of 23/06/2025:
1. Planned and unplanned attendances to ED, Plaster Room or Fracture clinics measured using data collected in medical notes at one timepoint
2. Additional use of plain radiograph imaging measured using data collected in medical notes at one timepoint
3. Recovery of mobility (time to weight bear) measured using proxy reporting on days 7 and 28
4. Use of additional treatments measured using data collected in medical notes at one timepoint
5. Requirement for oral analgesia measured using proxy reporting at day 7
6. Resource use at 28 days and contact with other NHS services measured using proxy reporting
7. Satisfaction with allocated treatment measured using a parent-completed Likert scale at 28 days
8. Complications, including: a) Pressure ulcers resulting from the use of devices designed and applied for diagnostic or therapeutic purposes category 1-4; b) Fracture displacement requiring further treatment measured using data collected in medical notes at one timepoint

Previous secondary outcome measures:
1. Planned and unplanned attendances to ED, Plaster Room, GP or Fracture clinics measured using data collected in medical notes at one timepoint
2. Additional use of plain radiograph imaging measured using data collected in medical notes at one timepoint
3. Recovery of mobility (time to weight bear) measured using proxy reporting on days 7 and 28
4. Use of additional treatments measured using data collected in medical notes at one timepoint
5. Requirement for oral analgesia measured using proxy reporting at day 7
6. Resource use at 28 days and contact with other NHS services measured using proxy reporting
7. Satisfaction with allocated treatment measured using a parent-completed Likert scale at 28 days
8. Complications, including: a) Pressure ulcers resulting from the use of devices designed and applied for diagnostic or therapeutic purposes category 1-4; b) Fracture displacement requiring further treatment measured using data collected in medical notes at one timepoint

Overall study start date
01/01/2024

Completion date
31/10/2027

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 23/06/2025:
1. Children aged from 9 months to their 4th birthday at the time of initial presentation to the hospital
2. Clinically suspected or confirmed toddler's fracture of the tibia as determined by standard guidelines at the recruiting site.

Previous participant inclusion criteria:
1. Children aged 9 months - 3 years
2. Attending ED or Fracture clinic within 72 hours of injury
3. Radiologically confirmed toddler's fracture of the tibia on x-ray, with displacement <2mm at the apex of the deformity including spiral/oblique fractures, transverse or buckle fractures, with or without a non-displaced fibula fracture; OR, a clinically suspected toddler's fracture, as determined by standard guidelines at the recruiting site.

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Months

Upper age limit
3 Years

Sex
Both

Target number of participants
494

Key exclusion criteria
Current participant exclusion criteria as of 23/06/2025:
1. Suspected non-accidental injury requiring further imaging or investigation
2. Associated displaced fibula fracture
3. Comminuted/complex fracture patterns of the tibia
4. Physeal injuries of the tibia
5. Multiple fractures
6. Metabolic bone disease
7. Congenital anomalies involving the lower limb and foot (limb deficiencies)
8. Has previously participated in the ToTs Study

Previous participant exclusion criteria:
1. Non-accidental injury requiring further imaging or investigation
2. Multiple injuries
3. Associated displaced fibula fracture
4. Comminuted fracture patterns
5. Physeal injuries of the tibia
6. Metabolic bone disease
7. Congenital anomalies involving the lower limb and foot (limb deficiencies)

Date of first enrolment
30/09/2025

Date of final enrolment
30/03/2027

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Sheffield Childrens Hospital
Western Bank
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United Kingdom
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Sponsor information

Organisation
Sheffield Children’s NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website

https://www.sheffieldchildrens.nhs.uk/

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
Planned publication in a peer-reviewed journal

Intention to publish date
31/10/2028

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?
Protocol file	version 1.0	22/04/2025	13/06/2025	No	No