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ODD SOCKS - Outcomes of Displaced Distal tibial fractures - Surgery Or Casts in KidS

Submission date
05/02/2024

Recruitment status
Recruiting

Registration date
13/02/2024

Overall study status
Ongoing

Last Edited
15/11/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Broken ankles in children often involve the area from which the bone grows – the growth plate. Following growth plate injuries, the growth of the main shin bone in the lower leg (the tibia) can be altered permanently, which can cause the bone to not grow at all, or to grow wonky. Altered growth may affect how well the leg works. The younger the child at the time of injury (i.e. the more they have to grow), the worse the problem may become once the child has fully grown. There are different ways to treat this injury, but it is currently unclear whether one type of treatment is better than another. Some doctors believe that children with growth plate injuries need surgery to reset their bones to ensure that the growth plate is restored to its original position. They believe that this will lower the chance of abnormal growth. However, other doctors believe that attempting to reset the bones to restore the growth plate with surgery could bring about further damage. These doctors recommend the bones be treated in a plaster cast, without surgery to reset the bones. This study aims to look at whether when children aged between 8 and 15 years old break their ankles, surgery to reset the bones leads to better function than letting the bones heal using a plaster cast without resetting the bones. At the end of the study, the information will be combined about all the children that took part. This will help everyone to understand which treatment is best. To make sure people learn about the best treatment, the doctors who help with this study will talk to other doctors and other people in the NHS who write national guidelines. Patient co-investigators will help deliver the message to families and will be invited to share their experience of the study with medical professionals.

Who can participate?
Children aged between 8 and 15 years old who have a fracture through the growth plate at the bottom of the shin bone, where the bone ends have moved apart from each other.

What does the study involve?
In the study, half the children and young people will have their broken bones treated with surgery, whilst the other half will have a plaster cast with no surgery. Those who agree to join the study, with the support of their families, will be split fairly into two groups, using a research process called ‘randomisation’. Children will be assigned one of two treatments:
1. Surgical reduction – the children in this group will have an anaesthetic or be sedated so their bones can be reset in theatre, and a plaster cast put on their leg. Sometimes, if the doctor thinks

it necessary, wires, screws or a plate and screws will be inserted to hold the broken bones in position.
2. Conservative treatment – the children in this group will not have the bones reset in position, they will receive a plaster cast for support to allow the bones to heal naturally. The plaster casts will stay on for around 4-6 weeks for both treatments.

All children will be followed up for two years to keep track of their function, and the length and appearance of the leg. They will be asked about pain, whether they needed any more surgery, school attendance, complications, the number of hospital visits, their quality of life and satisfaction with treatment. Follow-up will occur at 6 weeks, 3, 6, 12 & 24 months. Participant follow-up will be organised by the University of Oxford – either electronically by email or text message or by telephone

What are the possible benefits and risks of participating?
Each of the two routinely used treatments has potential advantages and disadvantages.

1. Resting the leg in a plaster cast for up to 6 weeks, to allow it to heal by itself. The benefit is avoiding surgery. However, the growth plate is not in the perfect position, which may mean that it doesn't grow normally. This might cause a difference in the shape of the leg (i.e. the ankle could grow wonky) or the injured leg could become shorter than the uninjured leg. This may need future surgery to correct these problems and could cause pain and arthritis in the future.

2. Surgery to fix the bone, usually with screws and a plaster cast for up to 6 weeks. The benefit is that surgery puts the growth plate in the natural position, which many surgeons believe may help the leg grow normally. However, there are risks of surgery, such as the risk of an anaesthetic, infection, wound problems, pain or stiffness, injury to nerves supplying the foot and problems related to the metal implants. There is also still a chance that the leg doesn't grow normally, and often a need for a second operation to remove any metal implants.

Where is the study run from?
Alder Hey Children's NHS Foundation Trust is the sponsor for the study and has overall responsibility for the management of it. This study will be overseen by Oxford Clinical Trials Research Unit (OCTRU) with the day-to-day running of the study being completed by Oxford Trauma and Emergency Care at the University of Oxford.

The research team has a lot of experience in caring for children and young people with injuries and is active in health research. Parents and children have been involved in the development of this study, and are involved in the management.

When is the study starting and how long is it expected to run for?
September 2021 to May 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (Reference NIHR132675)

Who is the main contact?
Mr Nick Peterson: 0151 2284811, ODDSocks@ndorms.ox.ac.uk

Study website
https://www.oddsocks.org

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324571

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60457, IRAS 324571

Study information

Scientific Title
ODD SOCKS Study- Outcomes of Displaced Distal tibial fractures- Surgery Or Casts in KidS Study

Acronym
ODD SOCKS

Study objectives
This pragmatic randomised controlled trial aims to evaluate the clinical and cost-effectiveness of surgical reduction, compared to conservative treatment, for the management of displaced Salter Harris-II fractures of the distal tibial physis in children.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/01/2024, East Midlands - Nottingham 1 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8115, (0)207 104 8271, (0) 207 104 8089; Nottingham1.rec@hra.nhs.uk), ref: 24/EM/0006

Study design
Pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Internet/virtual, Medical and other records, Telephone

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
Childhood displaced Salter Harris-II fractures of the distal tibial physis

Interventions
The proposed project is a two-phased study. Phase 1 (internal pilot) will confirm the expected rate of recruitment and pilot data collection procedures in a large-scale multi-centre RCT. Phase 2 is the expansion of the internal pilot into the full definitive trial (main RCT). Phase 2 is the expansion of the pilot into the full definitive trial. A full trial report for the funder and peer-reviewed publications of the main results will be generated after the completion of this phase.

All children aged 8-15 years inclusive presenting to the trial centres with a displaced fracture of the distal tibia involving the physis and metaphysis (i.e. Salter-Harris II) are potentially eligible to take part. Upon presentation, children will receive analgesia and their ankles will be assessed to ensure that the fracture does not require an emergency realignment (i.e. compromising the blood or nerve supply to the foot, or causing potential damage to the skin and other soft tissue structures). Once any emergency realignment is either performed or confirmed to not be required, temporary immobilisation of the limb for comfort will be applied as per the usual practice of the treating centre. In many hospitals the decision related to definitive treatment is taken in the emergency department by the on-call orthopaedic surgical teams; in others the child may be discharged to an early appointment in the fracture clinic. Owing to the nature of the condition and treatment pathways, the study will be introduced to the patient at the point where definitive care is planned.

After informed consent/assent has been obtained, baseline demographic and injury data, physical function using the PROMIS Mobility CAT, pain intensity using the Wong-Baker FACES Pain Scale and health-related quality of life using the EQ-5D-Y will be collected.

The children will be split into two groups, using a research process called ‘randomisation’ using a computer randomisation service to fairly allocate treatments:

1. Surgical Reduction- the children in this group will have an anaesthetic or be sedated so their bones can be reset in theatre, and a plaster cast put on their leg. Sometimes, if the doctor thinks it necessary, a small cut will be made and wires, screws or a plate and screws will be inserted to hold the broken bones in position.

2. CONSERVATIVE TREATMENT group – the children in this group will not have the bones reset in position, they will receive a plaster cast for support and to allow the bones to heal.

After treatment, the parents and/or participants will be asked to complete further questionnaires at 6 weeks, 3 months, 6 months, 12 months and 24 months after randomisation.

Data will be collected primarily electronically (with a telephone interview where required) with email and/or text message prompts.
Participants will usually attend an orthopaedic follow-up clinic regularly, as part of standard care and until they are approximately 16 years old, or at least for 2 years after the initial surgery to monitor for signs of complications. In both groups, children will have up to two additional X-rays to what they would have if they were not taking part in this study.

Intervention Type
Procedure/Surgery

Primary outcome measure

To determine whether children treated with surgical correction have improved function compared with children treated with conservative care measured using the PROMIS Mobility questionnaire, at 24 months post-randomisation

Secondary outcome measures
The following secondary outcome measures will be assessed during the first 2-years post-randomisation between surgical reduction and conservative treatment:
1. Function measured using the PROMIS-Mobility Score at 6 weeks, 3, 6 and 12 months post-randomisation
2. Pain scores measured using the Wong-Baker faces pain rating scale at 6 weeks, 3, 6, 12 and 24 months post-randomisation
3. Quality of life measured using EQ-5D-Y at 6 weeks, 3, 6, 12 and 24 months post-randomisation
4. Complication rate measured using data collected in medical records at 6/8 weeks, 12 and 24 months post-randomisation
5. Satisfaction with cosmetic appearance of the leg measured using the Visual Analogue Scale (VAS) of cosmesis at 3, 12 and 24 months post-randomisation
6. Satisfaction with the treatment received measured using a Likert Scale at 3, 12 and 24 months post-randomisation
7. Child educational participation recording educational absences measured using a parent-reported questionnaire at 6 weeks, 3, 6, 12 and 24 months post-randomisation
8. Leg Length Measurement measured using the 'Tape Measurement Method' by a clinician at 12 and 24 months
9. Angular deformity and PPC (growth arrest) measured using radiographic images 24 months post-randomisation
10. Resource use measured using a bespoke electronic resource use questionnaire, and parental absence from work at 6 weeks, 3, 6, 12 and 24 months post-randomisation

Overall study start date
01/09/2021

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Aged 8 to 15 years old inclusive
2. There is radiographic evidence of a displaced fracture of the distal tibia involving the physis and metaphysis (Salter Harris II); with or without a corresponding fibula fracture
3. The treating clinician believes that they may benefit from surgical reduction +/- fixation

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Planned Sample Size: 192; UK Sample Size: 192

Key exclusion criteria
1. The injury is more than 7 days old
2. The fracture is open
3. They have an intra-articular fracture that requires fixation to restore the joint surface
4. They have any other contralateral (Opposite-sided) ankle fracture/injury
5. There is evidence that the patient and/or parent/guardian would be unable to adhere to trial procedures or complete follow-up
6. The patient has previously been enrolled on the ODD SOCKS Study

Date of first enrolment
22/05/2024

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place

Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Macclesfield District General Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Basingstoke and North Hampshire Hospitals
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Kent and Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Northwick Park Hospital
Watford Road
Harrow

United Kingdom
HA1 3UJ

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

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

Study participating centre
St Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

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

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Southampton General Hospital
Tremona Road
Southampton

United Kingdom
SO16 6YD

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St. Peters Road
Margate
United Kingdom
CT9 4AN

Study participating centre
Whiston Hospital (site)
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
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United Kingdom
PR2 9HT

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
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IP33 2QZ

Study participating centre
Betsi Cadwaladr Uhb
Royal Alexandra Hospital
Marine Drive
Rhyl
United Kingdom
LL18 3AS

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Mersey and West Lancashire Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

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

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Birmingham Women's NHS Foundation Trust
Birmingham Womens Hospital
Metchley Park Road
Birmingham
United Kingdom
B15 2TG

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
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Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

Sponsor details
Sponsorship Office, Clinical Research Business Division
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United Kingdom
L14 5AB
+44 (0)151 252 5570
research@alderhey.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

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 study protocol will be published in an open-access peer-reviewed journal following the Standard Protocol Items: Recommendations for Interventional Trials statement (SPIRIT, www.spirit-statement.org/). The study results will be published in an open-access journal, following the NIHR's policy on open-access research. The study will be reported following the CONSORT including any applicable extensions to this. The Template for Intervention Description and Replication (TIDieR) statement will be used for reporting the intervention.
The statistical analysis plan will be published in an open-access journal before recruitment is completed.
The health economics analysis plan will be published in an open-access journal before recruitment is completed.

Intention to publish date
01/11/2029

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