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Amongst children with a slipped capital femoral epiphysis, does keyhole surgery to stabilise the bone or major surgery to reconstruct the bone give the best outcome at 2 years?

Submission date
15/05/2023

Recruitment status
Recruiting

Registration date
19/05/2023

Overall study status
Ongoing

Last Edited
23/08/2024

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

A slipped capital femoral epiphysis (SCFE) is a rare condition but is one of the most important children's and adolescent hip disorders. SCFE is the most common reason for hip replacement surgery in adolescence and early adulthood. The number of children and young people with this condition is increasing, as there is strong evidence to suggest it is principally caused by obesity. A survey of almost 100 surgeons from the British Society for Children's Orthopaedic Surgery prioritised this as their most important research question.

The simplest explanation of the disease is to imagine the hip like a ball of ice cream (the top of the hip) on an ice cream cone (the thigh bone). As a result of the disease, the ice cream ball could melt and slip a little away from the cone (minor slip) or slip a lot (severe slip) or could just come loose from the cone completely (unstable slip). Unstable slips are particularly worrisome as the supply of blood, which gives the bone nutrition and oxygen to remain healthy, could stop completely, which may cause the whole hip to die (with the ice cream ball becoming very squashed).

The treatment of SCFE always involves surgery to stabilise the slip, however, which type of surgery is necessary depends on how bad the slip is. In mild slips, surgery involves inserting a screw using keyhole surgery, to stop the hip slipping any more (this is called 'stabilising'). For severe slips, where the hip bone is most deformed, doctors currently can choose between two types of operation and it is not clear whether one is better than the other. The first treatment option is inserting a screw through keyhole surgery (stabilising but not putting the ice cream back on the cone) and accepting that the shape of the hip has changed. This may cause problems with walking and may risk later osteoarthritis. The second option is to correct the slip through major surgery (stabilising and putting the ice cream back on the cone). However, this could make the hip unstable and carries a risk that the hip bone may disintegrate (i.e., a very squashed ice cream) causing disability.

The main aim of the study is to determine whether children treated with acute correction have improved function compared with children treated with pinning in situ after 2 years.

Who can participate?
Children aged between 8 and 15 years old with a stable severe SCFE

What does the study involve?
Participants are randomly allocated to one of the two treatments. During their recovery, participants will be seen for routine clinical follow-up at their treating hospital and will be contacted by text message and/or email on five further occasions (8 weeks, 3, 6, 12 and 24 months after enrolment). They will be asked questions about pain, activities, feelings, hospital attendance, school attendance and costs that they may have incurred in relation to this hip problem (e.g., days absent from work.)

What are the possible benefits and risks of participating?
The study compares the two treatments commonly used in the NHS. Each of these routinely used treatments has potential advantages and disadvantages.
Corrective surgery to improve the shape and stabilise the hip with screw(s) will correct the hip back to its natural position, which surgeons believe should improve hip movement and function. The main risk is damaging the blood supply feeding the hip, which may cause the hip to squash and change shape, which could cause early arthritis. This could cause problems with walking and may risk later arthritis and the need for further surgery in early adulthood.
Keyhole surgery to stabilise the hip with screw(s) without correcting the deformity can avoid major surgery in the short term and minimise the chance of damage to the blood supply feeding the hip. The main risk is that the child may suffer from pain or have problems with activities as the shape of the hip is not normal. This could cause problems with walking and may risk later arthritis and the need for further surgery in early adulthood.
There will be extra surveys and questionnaires to complete.

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 (UK)

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

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

Who is the main contact?
Prof. Daniel Perry, BigBOSS@ndorms.ox.ac.uk

Study website
https://bigboss-study.digitrial.com/

Contact information

Type(s)
Scientific

Contact name

Prof Daniel Perry

ORCID ID
http://orcid.org/0000-0001-8420-8252

Contact details
University of Liverpool
Dept Child Health
Alder Hey Children's NHS Foundation Trust
Alder Hey Children's Hospital
Eaton Road
Liverpool
United Kingdom
L14 5AB
+44 (0)151 282 4661
danperry@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320616

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55962, IRAS 320616

Study information

Scientific Title
The Big BOSS Study - The British Orthopaedic SCFE Surgery Study for Severe Stable Slips

Acronym
Big BOSS

Study objectives
Children treated with major surgery to correct and protect the hip have improved function compared with children treated with keyhole surgery, which protects the hip but does not correct the shape?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2023, South West - Cornwall & Plymouth Research Ethics Committee (No address provided; +44 (0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), ref: 23/SW/0047

Study design
Randomized; Interventional; Design type: Treatment, Imaging

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
Slipped capital femoral epiphysis (SCFE)

Interventions
The proposed project is a two-phase trial.

Phase 1 (internal pilot) will take place at a minimum of 20 centres and will confirm the expected rate of recruitment and data collection procedures. It will also optimise the procedures for recruitment through an integrated qualitative study – the Big BOSS Information Study. This will explore communication about the trial and the acceptability of the trial to families. The findings will be used to enhance trial procedures and information for patients, their parents and healthcare professionals.

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 recruitment centres with a severe stable SCFE are potentially eligible to take part. Upon presentation, children will be treated as per the standard practice of the treating centre.

After informed consent/assent has been given, 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’ to fairly allocate treatments. Randomisation will be 1:1 to either pinning in-situ or acute correction using a computer-based randomisation system. Randomisation allocation will be implemented using a minimisation algorithm with stratification factors: age group (8-10 years, 11-15 years) and current/previous opposite-sided SCFE (presence or absence).
1. Major surgery: children will have an operation under a general anaesthetic. Whilst asleep,

children have surgery to correct the shape of the hip bone associated with the SCFE. The hip will then be stabilised with a screw(s) to protect against future SCFE.
2. Keyhole surgery: children will have an operation under a general anaesthetic. Whilst asleep, children have surgery to stabilise the hip with a screw(s) to protect against worsening SCFE. Surgeons will not attempt to correct the shape of the hip associated with the SCFE.

After treatment, the parents and/or participants will be asked to complete further questionnaires at 8 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. No additional visits or procedures are required as part of the study protocol at any follow-up time point.

The researchers will also invite patients to consent to data sharing with the Non-Arthroplasty Hip Registry, which will enable the long-term results of the treatments under investigation.

A full trial report for the funder and peer-reviewed publications of the main results will be generated after the completion of phase 2.

Intervention Type
Procedure/Surgery

Primary outcome measure
Function measured using the PROMIS Mobility Tool at 24 months post randomisation

Secondary outcome measures
1. Function measured using the PROMIS Mobility Tool at baseline, 8 weeks, 3, 6 and 12 months post-randomisation
2. Pain measured using the Wong-Baker FACES pain rating scale at baseline, 8 weeks, 3, 6, 12 and 24 months post-randomisation
3. Quality of life measured using EQ-5D-Y at baseline, 8 weeks, 3, 6, 12 and 24 months post-randomisation
4. Satisfaction with care is measured using a satisfaction score at 8 weeks and 24 months post-randomisation
5. Educational participation is measured using a bespoke days of missed educational attendance questionnaire at baseline, 8 weeks, 3, 6, 12 and 24 months post-randomisation
6. Cost-effectiveness of treatments measured using Healthcare and Personal Resource use, absence from work, purchased childcare and EQ-5D-Y questionnaires at baseline, 8 weeks, 3, 6, 12 and 24 months post-randomisation
7. Complication rate measured using a bespoke complications questionnaire at 8 weeks, 12 and 24 months post-randomisation

Overall study start date
01/11/2021

Completion date
31/10/2027

Eligibility

Key inclusion criteria
1. Aged 8 to 15 years old inclusive
2. There is radiographic evidence of a SCFE*
3. The child is able to walk with or without the use of crutches or walking aids (i.e., the SCFE fulfils the 'Loder' definition of 'Stable')
4. The magnitude of the SCFE is severe; such that the treating clinician believes that it will cause significant femoroacetabular impingement

*NB: Patients with opposite SCFE that is concurrent (new) or fixed previously (old) can be included (as long as they have not previously been included in the BigBOSS study). If the opposite-sided hip is concurrent, the most severe hip will be considered the hip of interest.

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. There is evidence that the patient and/or parent/guardian would be unable to adhere to trial procedures or complete follow-up
2. The patient has previously been enrolled into the Big Boss Study

Date of first enrolment
02/11/2023

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

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

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Leeds Children's Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

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

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

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Robert Jones & Agnes Hunt Orthopoedic Hospital
Gobowen
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Royal Aberdeen Children's Hospital
Westburn Drive
Aberdeen
United Kingdom
AB25 2ZG

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

Study participating centre
Royal Alexandra Children's Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill

Stanmore
United Kingdom
HA7 4LP

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Sheffield Children's Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
University Hospital Coventry
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre

Bristol Royal Hospital for Sick Children
St. Michaels Hill
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Evelina Children's Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH

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

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

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford

United Kingdom
CM1 7ET

Study participating centre
Southend University Hospital
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

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

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

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

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

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

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

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131176

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2029

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Other publications	Editorial	01/02/2024	01/02/2024	Yes	No