

# 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?

<b>Submission date</b> 15/05/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/05/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/08/2024	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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.digitaltrial.com/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Daniel Perry

**ORCID ID**

<http://orcid.org/0000-0001-8420-8252>

**Contact details**

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**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](mailto: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**

Marlon 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 Orthopaedic 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  
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United Kingdom  
L14 5AB  
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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?
<a href="#">HRA research summary</a>			20/09/2023	No	No
<a href="#">Other publications</a>	Editorial	01/02/2024	01/02/2024	Yes	No