

British orthopaedic surgery surveillance study

Submission date 12/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/04/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Slipped Capital Femoral Epiphysis (SCFE) is hip condition that occurs during childhood. It occurs when the ball at the head of the femur (thighbone) slipping off the neck of the bone in a backwards direction, causing pain, stiffness and instability in the affected hip. Perthes' disease is another childhood disorder which affects the ball at the head of the femur. In Perthes' disease, the blood supply to the growth plate at the end of the femur becomes inadequate, causing the bone to break down (degeneration). Both of these conditions often require surgical treatment, and both are common causes of early osteoarthritis (a common form of arthritis) of the hip in adulthood. There is no good evidence to determine what causes either Perthes' Disease or SCFE, or what the best treatments are. The choice of treatment of either disease is dependent on the beliefs of the treating surgeon, rather than scientific evidence. In addition, the rareness of the diseases, and the emergency nature of surgery in SCFE are slowing down progress. This study aims to collect nationwide data about these two conditions in order to establish how common the diseases are, risk factors and different treatment options in order to improve future treatment and management options.

Who can participate?

Individuals with SCFE or Perthes' disease

What does the study involve?

In the first part of the study, each participating centre is asked to enter anonymised case details into a central database of all cases of Perthes' disease and SCFE that they treat at their centres. This allows the study team to determine how common each of the diseases are and what the different treatment strategies are across the UK. Further information is added after three months and two years for patients with SCFE and after one and two years for patients with Perthes' disease.

In the second part of the study, a subset of patients agree to take part and complete questionnaire after three months and two years for patients with SCFE and after one and two years for patients with Perthes' disease about their quality of life.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Alder Hey Children's NHS Foundation Trust and 143 other NHS Trusts across England, Scotland and Wales (UK)

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

January 2016 to September 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Prof Daniel Perry

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Contact information

Type(s)

Scientific

Contact name

Prof Daniel Perry

Contact details

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Additional identifiers

Protocol serial number

UoL001157

Study information

Scientific Title

Investigating childhood hip diseases (Slipped capital femoral epiphysis and Perthes' disease) as childhood precursors to osteoarthritis of the hip in adulthood: A nationwide anonymised surveillance cohort, and nested-consented cohort study

Acronym

BOSS

Study objectives

The aim of this study is to conduct a nationwide cohort of SCFE and Perthes' disease to determine the disease incidence, case mix, risk factors, variations in surgical interventions, and to determine the safety and efficacy of different surgical strategies.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East London and The City Research Ethics Committee, 20/01/2016, ref: 190754

Study design

Nationwide observational cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Slipped capital femoral epiphysis (SCFE), Perthes' disease

Interventions

Surveillance Cohort Study

A consecutive anonymised comprehensive surveillance cohort encompassing all UK cases of SCFE and Perthes' disease. Each participating centre is asked to enter anonymised case details into a central database of all cases of Perthes' disease and SCFE that they treat at their centres. This will allow the study team to determine incidence of the diseases and what the different treatment strategies are across the UK. Individual patient consent is not required for this part of the study, with minimal identifiers collected to protect confidentiality. After inclusion into the study, follow-up is recorded using routine medical records at the following intervals: SCFE - 3 months and 2 years, Perthes' - 1 and 2 years.

Nested consented cohort

A subset of the surveillance cohort in designated centres will be invited to participate in a consented sub-study. In this sub-study, patients provide consent to collect patient reported outcomes at admission, 3 months and 2 years (SCFE) and, diagnosis, 1 year and 2 years (Perthes'). Participants also have the option to consent to long-term follow-up.

Intervention Type

Other

Primary outcome(s)

Anonymised Surveillance Cohort:

Incidence of each disease within the UK is determined by expressing the cases seen as a proportion of the 'at risk' population. The 'at risk' population will be derived from government statistics. In order to ensure that the data collection mechanism is sensitive, a national independent network of orthopaedic surgical trainees (the BONE collaborative), and national routine administrative data provided by HSCIC is used to identify missing cases, and prompt their imputation into the cohort.

Nested Consented Cohort

Quality of Life is measured using the Pediatric Quality of Life Inventory (PEDSQL) at baseline, 3 months (SCFE only), 1 year (Perthes' disease only) and 2 years (both diseases).

Key secondary outcome(s)

Anonymised Surveillance Cohort:
SCFE

1. Radiographic Severity (Alpha angle) is assessed by reviewing radiographs that form part of the routine medical record at 2 years
2. Frequency of Avascular Necrosis is assessed by review of routine medical records at 3 months and 2 years, and by reviewing radiographs that form part of the routine medical record at 2 years
3. Frequency of Contralateral slip is assessed by review of routine medical records at 3 months and 2 years, and by reviewing radiographs that form part of the routine medical record at 2 years
4. Frequency of Chondrolysis is assessed by review of routine medical records at 3 months and 2 years, and by reviewing radiographs that form part of the routine medical record at 2 years

Perthes' Disease

1. Radiographic Outcome (Stulberg Outcome) is assessed by review of routine medical records at 2 years, and by reviewing radiographs that form part of the routine medical record at 2 years
2. Frequency of contralateral disease is assessed by review of routine medical records at 2 years, and by reviewing radiographs that form part of the routine medical record at 2 years

Nested Consented Cohort

Both Diseases (2 years)

1. Pain is measured using the Wong-Baker Faces Pain Score at baseline, 3 months (SCFE only), 1 year (Perthes' disease only) and 2 years (both diseases)
2. Quality of life is measured using the EQ5DY questionnaire at baseline, 3 months (SCFE only), 1 year (Perthes' disease only) and 2 years (both diseases)

Completion date

01/03/2020

Eligibility

Key inclusion criteria

SCFE:

1. Skeletally immature individuals
2. Radiological confirmation of displacement of the epiphysis relative to the metaphysis occurring at the proximal femoral physis
3. Newly presenting to secondary/ tertiary care during the study period with the above radiographic changes in either hip (i.e. patients will be included if the other side has been affected outside the study period, but the opposite hip is newly affected)
4. Undergoing surgical stabilisation during hospital admission
5. Resident within the England, Scotland or Wales

Perthes:

1. Skeletally immature individuals.
2. Any of the following radiographic features within the femoral epiphysis. Features may be evident on plain radiographs, or MRI.
 - 2.1. Flattening
 - 2.2. Sclerosis
 - 2.3. Fragmentation
 - 2.4. Collapse
 - 2.5. Reossification

3. Newly presenting to secondary/ tertiary care during the study period with the above radiographic changes in either hip (i.e. patients will be included if the other side has been affected outside the study period, but the opposite hip is newly affected)
4. Usually resident within the England, Scotland or Wales

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

857

Key exclusion criteria

SCFE:

Previous attempts at stabilisation of the currently affected hip.

Perthes:

1. Previous treatment for developmental hip dysplasia (not including double nappies)
2. Previous chemotherapy for malignancy
3. Previously diagnosed sickle cell anaemia
4. Multiple Epiphyseal Dysplasia (MED) or Spondyloepiphyseal Dysplasia (SED).
5. A known coagulopathy
6. Gauchers disease
7. Previous same-sided hip fracture
8. Hypothyroidism

Date of first enrolment

04/04/2016

Date of final enrolment

30/09/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
United Kingdom
L14 5AB

Sponsor information

Organisation
University of Liverpool

ROR
<https://ror.org/04xs57h96>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from danperry@liverpool.ac.uk

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Perthes' disease epidemiology and two-year outcomes	01/04/2022	04/04/2022	Yes	No
Results article	slipped capital femoral epiphysis epidemiology and two-year outcomes	01/04/2022	04/04/2022	Yes	No
Protocol article	SCFE protocol	01/03/2020	12/05/2020	Yes	No
Protocol article	protocol	01/03/2020	12/05/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes