ISRCTN54477575 https://doi.org/10.1186/ISRCTN54477575

British orthopaedic surgery surveillance study

Submission date
12/04/2017

Recruitment status
No longer recruiting

Registration date
19/04/2017

Overall study status
Completed

Last Edited
04/04/2022

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
D.C.Perry@liverpool.ac.uk

Study website
http://www.boss.surgery/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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 measure
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).

Secondary outcome measures
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 rview 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)

Overall study start date
01/03/2015

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

Age group
Child

Sex
Both

Target number of participants
The surveillance cohort will recruit for a period of 1 year (of full centre engagement) to determine incidence of the diseases under study. The nested consented cohort will require 300 cases of each disease to enable meaningful comparisons to be made within subgroups.

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
England

United Kingdom

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

Sponsor information

Organisation
University of Liverpool

Sponsor details
Clinical Research Governance Officer
University of Liverpool / Liverpool Joint Research Office
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3 Brownlow Street
Liverpool
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United Kingdom
L69 3GL

Sponsor type

University/education

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

Publication and dissemination plan
Patients and public:
Material for dissemination will be developed in conjunction with the patient panel, the NIHR CRN: Children 'Young Peoples Advisory Group' and STEPS and the Perthes' Association; UK charities. STEPS and the Perthes' Association have agreed to communicate the outcomes of the research via their newsletter, website and information packages. For the wider public it is planned that the INVOLVE national advisory group will be an important liaison throughout, with dissemination adhering to the 'make it clear' guidance. Following the recommendations of the 2013 'GenerationR' report, written feedback will be offered to study participants, which is produced in accordance with the advisory groups (above). This will enable participants to gain appreciation of the contribution they have made to the research, and how this has positively influenced the care of others.

Specialists & Generalists:
Early in the study the detailed protocol will be published in an open access journal to make it widely accessible to the medical community. Each annual meeting of the British Society of Children's Orthopaedic Surgery (BSCOS) will contain a breakout meeting to engage with the UK

orthopaedic community regarding study recruitment. On completion of the study, results will be formally presented to BSCOS and the British Orthopaedic Association (BOA). Results will be written for high impact journals, to target the both the specialist audience, and the generalist.

Policy makers:
NICE have issued recommendations for a study of this nature, and have emphasised their support for this study. The results will therefore have immediate impact on SCFE care through the development of NICE recommendations, made in conjunction with the specialist societies (BOA & BSCOS).

Intention to publish date
31/12/2020

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?
Protocol article	SCFE protocol	01/03/2020	12/05/2020	Yes	No
Protocol article	protocol	01/03/2020	12/05/2020	Yes	No
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