Long-term results of surgical treatment of Slipped Capital Femoral Epiphysis in the Netherlands

Published: 28-08-2013
Last updated: 26-04-2024

Primary objectiveThe primary objective is to evaluate the long-term functional outcome and the prevalence of osteoarthritis in patients surgically treated for SCFE between 1980-2002 in The Netherlands. We hypothesize a correlation between the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON37001

Source
ToetsingOnline

Brief title
LongTermSCFE

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Epiphyiolysis, Slipped femoral head

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Long-term, SCFE, Treatment

Outcome measures

Primary outcome

The main parameters are radiographic evaluation of the hip joint, range of

motion and impingement examination.

Secondary outcome

Secondary parameters are HOOS, EQ5D, Harris Hip Score and SF-36 questionnaires

Study description

Background summary

Slipped Capital Femoral Epiphysis (SCFE) is the most common traumatic hip disorder in adolescents, and it has a prevalence of 10.8 cases per 100,000 children1. SCFE is the loosening or separation, either partial or complete, of the epiphysis of the femoral head. SCFE occurs in children 10 to 17 years, and males account for 60% of the cases.
In the Netherlands this results into an incidence of 20-40 new cases per year, a number that seems to be increasing every year with an increasing number of obese children in our society. Murray et al found that the incidence of SCFE increased two and a half times in the last two decades, from 3.78 per 100.000 children in 1981 to a 9.66 per 100.000 in 2000 in the UK.
Although the etiology of SCFE remains unclear, it has been shown that obesity, the male gender, some systemic disorders and endocrine abnormalities are risk factors for development of the condition.
The current classification of SCFE includes stable and unstable slip. A stable SCFE is defined as one where the child is able to ambulate, with or without crutches. An unstable SCFE is defined as one where the child cannot ambulate at all. This classification system is predominantly based on patient history and complaints and not on physical examination, radiographs or ultrasound.
Once SCFE is diagnosed, treatment is indicated to prevent progression of the slip. For a stable SCFE; a single screw in situ fixation is still regarded the gold standard. For unstable SCFE; urgent but gentle reduction and internal fixation, with or without decompression is commonly advocated.2,12
In case of a mild to severe slip, open reduction and screw or pin fixation can be considered to improve joint congruity and prevent for early onset secondary

osteoarthritis.

The treatment of SCFE has been extensively described by many authors. However, few studies report the results of treatment at long-term follow-up. Wensaas et al. evaluated sixty-six patients with a follow up of 38 years and reported a correlation between the severity of the slip, the etiology of the slip (chronic or acute) and the long term results using radiographic evaluation, the EQ-5D questionnaire and the Harris Hip Score. Severe chronic and acute (bilateral) slips have a poor long term outcome. Of all patients included in this study with severe chronic and acute slips, 71% was given a total hip replacement due to long term complications: 60% of the patient due to avasculair necrosis of the femoral head, 20% of the patients due to Osteoarthritis and 20% of the patients due to a low Harris Hip Score (69 points).
Hansson et al concluded that patients with mild slips have a better outcome on long term then patients with a severe slip, but further long term studies are required, especially on the choice between in situ pinning and corrective osteomy for slips in excess of 50º.

Study objective

Primary objective
The primary objective is to evaluate the long-term functional outcome and the prevalence of osteoarthritis in patients surgically treated for SCFE between 1980-2002 in The Netherlands. We hypothesize a correlation between the severity of slip and the functional outcome, radiographic results and quality of life.
The methods we use are four questionnaires: Harris Hip score, SF-36, Oxford Hip score and HOOS, physical examination (range of motion examination and impingement) and radiographs (anterior-posterior and lateral) of the hips.

Secondary objective
The secondary objective is to evaluate possible radiographic signs of osteoarthritis. We expect to see a worse functional outcome and a lower quality of life in patients with radiographic signs of osteoarthritis.

Tertiary objective
The third objective is to identify possible risk factors for a worse functional outcome after in situ pinning, in order to be able to identify patients who might benefit from a primary open reduction or even correction osteotomy

Study design

A list of treated patients has already been extracted from the LUMC and JKZ/HAGA medical databases. All patient records have been checked, to see if they are complete and still up-to-date.

Patients from the (AMC, ErasmusMC, LUMC, MUMC, UMCG, UMCN, VUMC, WKZ) will be contacted by written request from their treating physician, inviting them to visit the outpatient clinic. Non-responders will be contacted by telephone one week after the letter is sent.
Patients will be asked to visit the outpatient clinic once; all of the measures will be performed during this visit and will take about one hour.
JKZ patients have all been contacted and a complete physical and radiological examination was already performed during clinical follow-up last year. The JKZ patient population will be contacted through their treating physician in order to complete the questionnaires.

Study Procedures

Radiographic evaluation:
Before the patient comes into the clinic (LUMC), we will request the pre- and postoperative taken radiographs from the medical archives to measure the southwick anterior-posterior angle. This has already been performed for all patients in the LUMC and JKZ/HAGA group.

A standard anterior-posterior radiograph is performed; using the standard positioning: The patient is supine, with the pelvis symmetrical for the examination of the hip joint; the knees are flexed over a small sandbag and a pressure pad is placed under the heels.
After the anterior-posterior positioning is taken, the radiographer confirms the position and takes
the anterior -posterior and lateral radiographs using the standard technique.8
This has already been performed for all patients in the JKZ/HAGA group.

After the radiographs are taken, they will be used to measure the tangent line on the anterior-posterior radiograph and to assess the Kellgren score on the anterior-posterior and measure the Alfa angle on the lateral radiograph. All radiographs will be scored by two blinded orthopaedic surgeons (one from the LUMC one from the JKZ/HAGA)

Physical examination:
Range of motion examination refers to the distance and direction the hip joint can move to its full potential. The examination will be an active and passive range of motion.
The range of motion of the hip will be tested in 6 directions: flexion, extension, abduction, adduction, medial rotation and lateral rotation
After the range of motion examination, the hip joint will be tested for impingement through two provocative hip pain tests, one for the front of the hip joint and one for the back.
When the impingement tests are finished, the trendelenburg sign and Duchenne walk will be tested by watching the patient walking and standing on one foot. Discrepancy is evaluated clinically. This has already been performed for all patients in the JKZ/HAGA group.

Questionnaires:
Hip function and impairment will be evaluated using the HOOS, EQ5D, Harris Hip score and SF-36 scores (Appendix 1). These questionnaires are subjective quality of life scores, which are filled out by the patient alone. Some patients were treated for bilateral SCFE. They need to fill an adjusted HOOS questionnaire. The principal investigator will assist when needed.

HOOS:
The HOOS (Hip disability and Osteoarthritis Outcome Score) questionnaire has proved to be valid for persons with hip disability with or without hip osteoarthritis and with high demands of physical function. The HOOS questionnaire includes 5 different parts: symptoms, pain, daily activities, sports and quality of life, with a total of 40 questions. Each question can be answered by filling in one of the five possible answers: from none to severe.

EQ5D:
EQ5D is a standardized questionnaire for use as a measure of health outcome for patients whit or without arthritis in order to provide a simple generic measure of health for clinical appraisal. The questionnaire includes 5 questions: mobility, self care, daily activities, pain/symptoms and mental health. Each question has 3 possible answers.

Harris Hip Score:
Hip function and impairment will be evaluated using the Harris Hip Score (HHS). The HHS is a combined questionnaire including two parts: A questionnaire and an observation list. The list is used as a diagnostic, prognostic or evaluating list to measure the physical impairment of the hip joint and the quality of life.
The HHS includes ten items with questions regarding last week. One item is about pain, seven items are about functioning in daily life, one item is about hip-deformities and one item is about the mobility of the hip. The maximum score is 100 points. (Good/excellent: 90-100, Good: 80-90, moderate: 70-80, insufficient: <70).

SF-36
The SF-36 is a multi-purpose, short-form health survey with 36 questions. It yields an 8-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group.

Non-relating medical findings
Participating patients will be asked in advance if they want tot be informed on unexpected medical findings not related to this study. If a unexpected medical finding is found patients will be invited to the clinic to inform them of these findings and their GP will be informed on this consult.

Study burden and risks

The European Union guidelines for radiation protection have been followed, minimizing the radiation risk for our patients, exposing them to effective doses of less than 0.1 mSv (adults). This category involves a risk (total detriment from the radiation exposure) for normal subjects of the order of one in a million or less.
This study will be performed within the values of the declaration of Helsinki and will be handed to the Science committee of the LUMC Radiology Department and METC for accreditation.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Treated for SCFE between 1980 and 2002 with and single or double screw in-situ fixation

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	147
Type:	Anticipated

Ethics review

Approved WMO Date:	28-08-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-01-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42099.058.12