Prospective Evaluation of Sports Activity and the Developemnt of Femoroacetabular Impingement in the Peadiatric Hip

Published: 22-08-2018
Last updated: 10-04-2024

This pilot prospective cohort study is designed to provide feasibility data for a large global study that will critically evaluate the impact of sport activity and FAI development during the critical phase of hip maturation.Primary Feasibility…

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

Summary

ID

NL-OMON46741

Source
ToetsingOnline

Brief title
PREVIEW

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Cam morphologie, Femoroacetabular Impingement (FAI)

Research involving
Human

Sponsors and support

Primary sponsor: McMaster University Hospital

Source(s) of monetary or material Support: Gesponsord door de McMaster University;department of orthopaedics. Er is een academische grant van Conmed voor deze studie. Er is GEEN sponsorgeld van 'de industrie' betrokken bij deze pilot studie

Intervention

Keyword: Aetiology, Femoroacetabular impingement, Hip, Sports

Outcome measures

Primary outcome

Feasibility Outcomes:

Several aspects of feasibility will be assessed including rates of participant enrollment and protocol compliance. Rates of participant enrollment will be assessed by comparing projected and actual participant enrolment at each pilot clinical site. We will carefully document any issues with compliance with the protocol which will include missing case report form data and incomplete participant follow-up at 2 years. Additionally, we will closely monitor the completion of outcome measures including the Habitual Activity Estimation Scale (HAES)25, Hip Outcome Score (HOS)26, and Paediatric Quality of Life Inventory (PedsQL)27 and documentation of adverse events at the initial and final follow-up assessments.

Primary Study Outcome (Secondary Objective): The primary study outcome is the incidence of radiographic cam morphology between the highly active (including sports) exposure subjects and the inactive/less active control subjects at 2 years, as determined by the dedicated MRI of the hip.

We will define activity levels using the HAES questionnaire. The HAES quantifies the duration, in hours, of 4 levels of activity ranging from very inactive (lying down, napping), somewhat inactive (sitting, reading, watching television, playing video games), somewhat active (walking, light chores), to very active (running, bicycling, activities leading to sweating or breathing hard) over a complete waking day. The HAES is designed for administration in the paediatric population and has been shown to be both a valid and reliable form of quantifying levels of physical activity. The exposure group (highly active, athletes) will include those that score *very active* on the HAES and report prior sporting activity. The control group will include those that score from *very inactive* to *somewhat active* and who report minimal to no prior sporting activity. A sensitivity analysis will evaluate cam morphology incidence (from baseline to 2 years) across all 4 possible scoring categories. Adult and child versions of the HAES questionnaire will be administered to ensure accuracy of reporting from subjects

Radiographic signs of FAI are common in asymptomatic individuals and will therefore be interpreted along with a detailed history and physical examination. Symptomatic FAI in children and adolescents is typically characterized by anterior hip pain aggravated by flexion activities, decreased hip internal rotation, and a positive impingement sign. For the purposes of this study, physical examination will include range of motion measurements documented in the supine position by the blinded local investigator or a research assistant (using a goniometer), as well as response of provocative hip

tests, specifically the anterior and posterior hip impingement tests on both hips28. The study hip considered for evaluation will be that on the subject*s dominant leg (i.e. right or left).

We will use a non-contrast 3D-volumetric interpolated breath-hold examination (VIBE) sequence MRI. This three dimensional protocol has been used to document FAI related morphology and minimizes both radiation exposure and eliminates the use intra-articular contrast injections for the asymptomatic study subject. The radiographic criteria to determine the presence of a cam morphology or other FAI morphology include:

1. An alpha angle greater than 50 degrees
2. A femoral head and neck offset ratio less than 4.5mm, where prior research has shown offset ratios in asymptomatic patients and those with cam impingement at 0.21 ± 0.03 and 0.13 ± 0.05 respectively
3. We will also document secondary signs of FAI including hernation pits at the femoral head and neck junction, chondral and labral lesions, and/or protrusio acetabuli (when the femoral head is overlapping the ilioischial line medially)

An independent, blinded Central Adjudication Committee (CAC) will review all MRIs and physical exam notes to characterize cam morphology according to these definitions. They will also evaluate any adverse events. This committee will be comprised of 2 orthopaedic surgeons with specialized expertise in diagnosing and treating FAI (Drs. Musahl and Gandhi) and 2 musculoskeletal radiologists

(Drs. Choudur and Mascarenhas). Any disagreements among the CAC members will be resolved during regular conference calls and/or in-person meetings. The CAC members will be blinded. All recruiting sites are asked to send coded, blinded MRI images to the Methods Centre for review.

Secondary outcome

Secondary Study Outcomes (Secondary Objective 2): Secondary outcomes include hip function and HRQL between subjects with a diagnosed hip deformity and no deformity at 2 years, as determined by the HOS and PedsQL questionnaires.

The HOS is a self-administered hip score that was designed to capture hip function. The HOS has been shown to have the greatest clinimetric evidence for use in patients with FAI or labral tears. The HOS was developed for young adults and has been shown to be appropriate for use in adolescents with hip impingement. It has been validated in the Dutch language. The PedsQL is a validated and responsive measure of HRQL in children and adolescents, and can be used with healthy children and those with acute and chronic health conditions. The PedsQL was specifically designed to measure the core health dimensions outlined by the World Health Organization (physical, emotional, and social functioning), which will ensure adaptability in the global study. Adult and child versions of the HOS and PedsQL will be utilized to ensure accuracy of reporting.

Study description

Background summary

Femoroacetabular impingement (FAI) is a recently described condition that causes hip pain and can lead to the development of osteoarthritis of the hip later in life. Some cross-sectional studies have estimated that the prevalence of hip impingement ranges from 14-17% among asymptomatic young adults to almost 95% among competitive athletes. FAI occurs as a result of a size and shape mismatch between the femoral head (ball) and the acetabulum (socket). FAI is typically classified into 2 subtypes; cam-type (a misshaped femoral head / cam morphology) or Pincer type (an over covered or deep socket). Most adult patients (18+ years) have a combination of both types of impingement. With FAI, the abnormal femoral head and acetabular rim of the hip joint collide or *impinge* during movements such as hip flexion and rotation. Typically, patients with this condition experience hip pain and loss of hip function. The development of hip pain in this manner serves as an indicator for early cartilage and labral damage, potentially resulting in hip osteoarthritis.

The number and diagnoses of FAI has recently risen across all age groups, but it has been especially notable within paediatric and adolescent populations. In the adult, FAI is most commonly attributed to an *idiopathic anatomic variant*. In the paediatric population, implicated causes of FAI have included genetics, subclinical paediatric hip disease, and stresses to the hip joint from high-intensity, repetitive activity typically attributed to certain sports. According to Packer et al., there is no definitive evidence that FAI is transmitted genetically, and in otherwise healthy children, there is growing evidence that FAI, particularly with cam morphology, has a higher prevalence in athletes who performed at a high level during adolescence.

Sports and the Development of FAI in the Paediatric Population
Over the past 20 years, sport injuries among children have dramatically increased, where more than 38 million young athletes participate in organized sports annually in US and of those, 3.5 million that receive medical treatment for their injuries are 14 years and younger. High impact and high intensity activity common in many sports have the potential to cause hip damage, especially during physeal closure in young children. Research is needed to determine *how much is too much* sport activity in order to advocate for the young who cannot easily protect themselves from excesses. This concern has been highlighted in publications addressing the potential deleterious impact of early sport specialization in young athletes.

High impact activities in combination with intensity of various kinds have been shown to affect the developing femur. Among children, open physes and growing cartilage make them more susceptible to injury and shear forces that can result in premature physeal arrest, apophyseal avulsion fractures, and chondral injuries. A higher prevalence of cam morphology (>50%), both symptomatic and asymptomatic, has been shown in adolescent athletes that play ice hockey,

basketball, and soccer when compared to controls that did not play sports. These sports involve repetitive deep flexion, flexion-adduction or extension-abduction movements, which bring the cam lesion on the femoral head or the pincer lesion on the acetabulum into conflict. Therefore, participating in high impact sports during growth likely plays an important role in the development of a cam deformity. This is concerning given the increasing trend toward year-round participation in youth sports with early specialization.

Preliminary Studies

Most studies in the current literature that evaluate the relationship between sports and the development of FAI are relatively small, retrospective case-controls. There are 2 recent systematic reviews on this topic that overlap in primary study data. There were up to 4 studies included across both reviews that were published since 2011 and evaluated varying sports and levels of training intensity through a meta-analysis. Both reviews describe an increased risk of development of a cam morphology in athletes that play ice hockey, basketball, soccer, and other jumping sports. In addition, adolescent males that train for these sports at least 3 times per week were at a greater risk than their non-athletic counterparts of developing femoral head-neck deformities associated with FAI.

The studies in these reviews were predominantly cross-sectional in design, with small sample sizes (wide confidence intervals), and did not describe changes in hip morphology during the critical phase in hip development and maturation. New evidence demonstrates conflicting results regarding how and when primary cam-type FAI develops in relation to skeletal maturity. Accordingly, the current literature notes the need for longitudinal or prospective MRI studies to understand the etiology of primary FAI development to identify preventive strategies, delineate radiographic values, define specific indications for operative management, and examine long-term outcomes to determine optimal management.

Significance

As FAI is diagnosed most frequently in athletes, and it is estimated that 30 to 45 million adolescents age 6-18 years old are involved in sports, it is becoming imperative to identify factors that may predict its development, study treatments, and improve outcomes. The presentation of a cam morphology can include hip pain, loss of function, and the need for surgical treatment along with its potential complications (complication rates of hip arthroscopy in children and adolescents range from 1.8-12.9%). Considering that research has demonstrated the connection between FAI and osteoarthritis in adulthood, potentially leading to the need for total hip replacement, it has now become critical to mitigate the risk of developing cam morphology at a young age. A prospective evaluation of the impact of sport activity, and the increasing tendency for sport specialization, in the very young athlete is important to protect the millions of adolescents involved in sports that may be at risk of

developing FAI

Study objective

This pilot prospective cohort study is designed to provide feasibility data for a large global study that will critically evaluate the impact of sport activity and FAI development during the critical phase of hip maturation.

Primary Feasibility Objective
To assess feasibility of a global prospective cohort study that will evaluate the association between the level and type of sport activity and the development of hip deformity in the paediatric population. In order to assess the feasibility of large-scale prospective cohort, we will conduct a 50-subject pilot study across multiple sites. Measures of feasibility will include rates of participant enrolment and protocol compliance (e.g. participant follow-up and completion of outcome measures).

Secondary Study Objective 1
To determine if the level and type of sport activity is associated with the development of hip deformities in the paediatric population at 2 years. Intensive sport training and specialization has been implicated in the development of abnormal hip morphology in adolescents. Certain sports (e.g. soccer, basketball, ice hockey, football) have also been identified as placing excessive stress on the hip and surrounding soft tissues, which bring the cam morphology on the femoral head and the pincer morphology on the acetabulum into conflict. We hypothesize that: 1) Participants engaging in high sport activity levels will have a higher prevalence of cam morphology diagnosed through three dimensional magnetic resonance imaging (3D MRI) of the dominant hip compared to non-athletes in the same age group (controls) at 2 years; and 2) Participants with specialized activity in certain sports (e.g. soccer, basketball, ice hockey, football) will have a higher prevalence of cam morphology diagnosed through MRI compared to non-athletes at 2 years.

Secondary Study Objective 2
To determine if the presence of hip deformity is associated with varying hip function and health-related quality of life (HRQL) in the paediatric population at 2 years. Hip morphology will be diagnosed through MRI of the dominant hip to avoid radiation exposure to the developing hip. For any impingement morphology (cam or pincer) identified, not all subjects may be symptomatic. We hypothesize that: 1) Participants diagnosed with cam morphology will have decreased function and HRQL at 2 years compared to those without; and 2) Participants with symptomatic cam morphology will have the lowest function and HRQL scores at 2 years compared to asymptomatic individuals.

Study design

This is a pilot prospective cohort study of 50 athlete and non-athlete participants (25 per group) between the ages of 12 and 14. Participants will be recruited from experienced hip surgeons and sports medicine researchers at multiple international clinical sites. Participants will be evaluated clinically and radiographically at baseline and again at the 2-year follow-up. The primary outcome for the overall pilot study is feasibility (Primary Feasibility Objective). We will also measure sport and general activity levels, function, HRQL, and will independently adjudicate hip morphology changes using MRI over 2 years (Secondary Study Objectives).

Study burden and risks

There are no known risks involved in our study, aside from the inconvenience of completing questionnaires. The magnetic resonance imaging does not involve any radiation and therefore the study procedure is safe for children. Participants will be made aware of potential risks in the informed consent form and during the consent process

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Age 12-14 years at baseline
Sex: 5 boys and 5 girls
Activity level: 5 highly active children and 5 sendentary controls

Exclusion criteria

Known hip pathology
Previous hip surgery
Contra-indication to undergo MRI

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	22-08-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL63530.078.18