Ten year follow-up study of anterior cruciate ligament ruptures in children.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON44126

Source
ToetsingOnline

Brief title
Ten year follow-up study of ACL ruptures in children.

Condition

- Joint disorders

Synonym
ACL; anterior cruciate ligement rupture

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ACL, children, follow-up, ruptures

Outcome measures

Primary outcome

The aim of the present study is to evaluate the long-term consequence of ACL ruptures in children, concerning radiological and clinical outcomes.

Primary Objective:

To evaluate the clinical outcomes concerning pain, knee function and knee related quality of life after ten years in patients who were diagnosed with an ACL rupture during childhood.

Secondary outcome

Secondary Objective(s):

1. To assess the presence of radiological osteoarthritis after ten years in patients who were diagnosed with an ACL rupture during childhood.
2. To assess the activity level after ten years in in patients who were diagnosed with an ACL rupture during childhood.
3. To assess the stability of the knee after ten years in patients in patients who were diagnosed with an ACL rupture during childhood.

Study description

Background summary

The anterior cruciate ligament (ACL) is one of the most commonly injured ligaments of the knee. The incidence of ACL injuries is currently estimated at approximately 200 000 annually, with 100 000 ACL reconstructions performed each year in the USA, and over 5000 ACL reconstructions per year in the Netherlands. The goal of the treatment of ACL ruptures is to obtain the best functional level for the patient without risking new injuries or degenerative changes in the knee. There are many factors to be considered when deciding whether an ACL rupture should be treated surgically or conservatively. Among these factors are the degree of instability, the presence of meniscal lesions, the patient*s level of athletic activity and the patient*s age.

At the moment there is no official registration system for ACL ruptures in children. Therefor the exact number of children with ACL ruptures in the Netherlands is unknown. However, the incidence of ACL ruptures in children seems to have increased in the last two decades. This is possibly due to increased participation in high activity sports, increased awareness or more frequent use of imaging tools.

In adults, injury to the ACL frequently leads to posttraumatic osteoarthritis (OA) and many surgeons had and have hope that ligament reconstruction also would lead to a reduction of post-traumatic OA. However, the prevalence of degenerative changes after reconstruction of the ACL ranges between 10* 87% (Jomha, 1999)).
Current evidence shows children with instability of the knee and meniscal tears are also at risk for developing OA. Though, a large long-term follow-up study is not available. More long-term follow is necessary to evaluate the influence of ACL ruptures on OA and functional outcome of the knee.

Study objective

Till date no (other) large long-term follow-up study of children with ACL ruptures has been published with a follow-up period of minimally 10 years. Therefor, the long-term consequences of ACL ruptures in children are still unknown, especially with regards to OA.
The aim of our study is to evaluate the long-term radiological and clinical outcomes of children with an ACL rupture.

Study design

The design of the study is a prospective cohort study, in which the radiological and functional outcomes of ACL ruptures in children will be evaluated. This is a ten-year follow-up study.

Study burden and risks

The burden is primarily time (visit of outpatient clinic, and to fill in

questionnaires). Also a limited amount of radiation is given by an x-ray of the knee. There is no direct benefit from participation or group relatedness.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

A patient who visited the Sophia Children's hospital between 2000 and 2005 and were diagnosed with an anterior cruciate ligament rupture

Exclusion criteria

posterior cruciate ligament ruptures

inability to speak Dutch

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-08-2016
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	NL54836.078.16