Anterior cruciate ligament reconstruction in patients with open physis: risk for growth abnormalities and outcome

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To determine the incidence of linear and angular growth disturbances following ACL reconstruction in patients with open physis.

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

Summary

ID

NL-OMON56392

Source
ToetsingOnline

Brief title
ACL reconstruction with open physis

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Growth disorder

Research involving
Human

Sponsors and support

Primary sponsor: OCON
Source(s) of monetary or material Support: OCON + MZH

Intervention

Keyword: Anterior cruciate ligament reconstruction, Children, Growth abnormalities, Open physis

Outcome measures

Primary outcome

The primary objective is to determine the incidence of linear and angular

growth disturbances following ACL reconstruction in patients with open physis.

Secondary outcome

Secondary objectives are the PROMS, clinemetrics, complications, failure rate.

And the incidence of growth disturbance plotted against the amount of growth

remaining at the time of ACL surgery and surgical technique. As well as to

determine the incidence of early growth disturbances and the influence of the

estimated residual growth and operative technique on growth disturbances.

Study description

Background summary

Anterior cruciate ligament (ACL) injuries in children create a high level of concern, as the incidence is rising rapidly and the consequences of this injury are magnificent with reduced activity levels, negative effects on knee-related quality of life, and risk of premature onset of posttraumatic osteoarthritis. The limited scientific evidence regarding the potential negative consequences of ACL reconstruction with an autologous tendon graft in the skeletally immature patients, is conducted in mostly small cohorts with infrequent use of the gold standard of radiography. This leads to a variable state of care, and requires clarification as ACL reconstruction does improve outcome compared to conservative treatment. In this study we want to determine the incidence of growth disturbances, to assist the patient and the orthopedic surgeon to make a more informed decision on the treatment plan.

Study objective

To determine the incidence of linear and angular growth disturbances following ACL reconstruction in patients with open physis.

Study design

Retrospective cohort study with prospectively collected data.

Study burden and risks

Patients in the first group will be recruited for a one-time outpatient visit to conduct all outcome measures, including radiographic analysis (bilateral lateral knee and long-leg radiograph), clinimetrics, self-reported functional outcomes and history taking regarding failure of ACL reconstruction, complications and subsequent re-operation . All these outcome measures are similar to the data collected during current-practice follow-up. Patients in the second group therefore will be reviewed retrospectively without undergoing any interventions as part of this study. If the potential risks of ACL reconstruction does not outweigh the previously established benefits, we might shift our practice to a more aggressive reconstructive approach in order to avoid the perils of conservative treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

- Proven primary ACL rupture, confirmed by means of history, physical examination and magnetic resonance imaging (MRI) for which ACL reconstruction with an autologous tendon graft was performed
- Open physis at time of surgery, based on the pre-operative radiograph
- Minimum follow-up of 1 year
- 16 years or older at the time of recruitment for the present study (only applicable to group 1)
- 12 years or older at the time of recruitment for the present study (only applicable to group 2)

Exclusion criteria

- Unable to understand Dutch language
- Contralateral ACL rupture, with open physis at time of ACL reconstruction
- Multiligamentous injury (lateral or medial collateral ligament > grade 2, posterior cruciate ligament > grade 1)
-Under 16 years of age at time of prospective data collection (only applicable to group 1)
-Under 12 years of age at time of retrospective data collection (only applicable to group 2)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2024
Enrollment:	115
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	20-12-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL84000.100.23