KNee osteoArthritis anterior cruciate Ligament Lesion study

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

Summary

ID

NL-OMON49832

Source
ToetsingOnline

Brief title
KNALL study

Condition

- Joint disorders

Synonym
knee ligament rupture, knee pain

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ISAKOS Grant

Intervention

Keyword: ACL injury, knee osteoarthritis

Outcome measures

Primary outcome

Clinical knee osteoarthritis

Secondary outcome

Radiographic knee osteoarthritis and progression of structural osteoarthritis

features on MRI.

Study description

Background summary

Anterior cruciate ligament (ACL) rupture is a strong risk factor for knee osteoarthritis. Unfortunately, there are no treatment options to prevent osteoarthritis development in subjects with ACL rupture. Being able to predict occurrence of osteoarthritis by relating early changes in symptoms and structural features to long-term disease development, will enable the identification of new treatment targets for orthopaedic surgeons that could prevent future knee osteoarthritis development. Also, it will allow for the identification of relevant subgroups of patients at high risk for future osteoarthritis development that could serve as target population for future trials.

Study objective

10 years ago we selected an unique cohort of 154 patients with acute ACL injuries, who were prospectively characterized over the first two years post-injury. A single follow-up measure within this established cohort is proposed, to those that gave written consent (N=152). Questionnaires, radiography and MRI will allow the evaluation of the natural course of structural and symptomatic knee osteoarthritis development. This data will also answer important questions like: Which group of patients are at increased risk for osteoarthritis development? Which early changes in symptoms and/or structures should be targeted to prevent osteoarthritis development?

Study design

Single observation extending the follow-up duration of a previously initiated prospective cohort study.

Study burden and risks

Participating in this study requires minimal effort from participants (visit to Erasmus MC, fill in the questionnaire, and undergo radiography, MRI and physical examination) at negligible risk.

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

- participated in the KNALL study
- written consent to be contacted for further research

Exclusion criteria

Not willing to participate

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-10-2020
Enrollment:	152
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-11-2020
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	NL73540.078.20