Long term follow-up of anterior cruciate ligament ruptures: bone-patellatendon-bone autograft reconstruction versus non-operative treatment.

Published: 12-03-2013
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To study the clinical and radiological outcomes 20 years after operative or conservative treatment for an ACL rupture

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON37182

Source
ToetsingOnline

Brief title
Long term results of ACL ruptures

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
ACL; anterior cruciate ligament

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: anterior cruciate ligament, bone-patellatendon-bone reconstruction, non-operative treatment

Outcome measures

Primary outcome

1. artrosis on the x-ray of the knee

2. clinical outcome scores of knee functionality (KOOS and Lysholm) and laxity

found with physical examination

Secondary outcome

1. activity level; tegner score

2. meniscal injuries

3. the number of (re-)operations

4. correlation of artrosis of the knee with general artrosis

Study description

Background summary

We conducted a case control study in which we compared the conservative teatment with the operative treatment for patients after an ACL rupture.(MEC 218.023/2002/227) The literature on longterm outcomes after ACL ruptures with radiological evaluation and also conservative treatment is scarce.

Study objective

To study the clinical and radiological outcomes 20 years after operative or conservative treatment for an ACL rupture

Study design

Long-term follow-up of a case-control study comparing operative with

conservative treatment for an ACL rupture. All patients will be asked to visit the outpatient clinic of the orthopedics department once for radiological and clinical evalution of the knee function.

Study burden and risks

The burden is primarly time (visit to the outpatient clinic) and radiation (three knee x-rays and one hand x-ray). There is no direct benefit from participation. Travel allowance will be offered to participants.

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

All patients included in our Case-Control study (MEC 218.023/2002/227) will be invited to participate.

Exclusion criteria

Not applicable

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	12-03-2013
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	NL42562.078.12