Revalidation after Anterior Cruciate Ligament Reconstruction

Published: 12-11-2008
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To compare two revalidation protocols with reference to the ACL reconstruction

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON37025

Source
ToetsingOnline

Brief title
revalidation after ACL reconstruction

Condition

- Tendon, ligament and cartilage disorders

Synonym
ACL rupture, ruptured anterior cruciate ligament

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: er is geen geldstroom voor het onderzoek anders dan de door de onderzoeker geinvesteerde tijd.

Intervention

Keyword: Anterior Cruciate Ligament, Outpatient, Reconstruction, Revalidation

Outcome measures

Primary outcome

1. Tegner knee score

2. Lysholm knee score

3. IKDC knee score

4. VAS score for pain

Secondary outcome

Return to the previous level of functioning (work, ADL activities)

Study description

Background summary

The subject of interest in this study is the revalidation after ACL reconstruction. Originally, the operation was followed by a long period of revalidation on an inpatient basis. Nowadays patients are dismissed from the hospital earlier or the operation is performed on an outpatient basis. In this situation the revalidation supervised by the physical therapist is started directly after the operation. In the literature no differences are reported between inpatient or outpatient patient groups with reference to function, time of recovery and pain reported by the patient.

Study objective

To compare two revalidation protocols with reference to the ACL reconstruction

Study design

Mono centre study design (Red Cross Hospital, Beverwijk, the Netherlands)
Prospective
Open study design
To compare two patient groups after ACL reconstruction. Randomisation for one of the two revalidation protocols. In the first protocol the operation is performed on an inpatient basis with 3 to 5 days of inpatient revalidation under supervision by the physical therapist. After this inpatient period, the revalidation is continued on an outpatient basis. In the second protocol the

patient is operated in an outpatient setting followed by outpatient revalidation for the moment of operation.

Intervention

To compare two patient groups after ACL reconstruction. Randomisation for one of the two revalidation protocols. In the first protocol the operation is performed on an inpatient basis with 3 to 5 days of inpatient revalidation under supervision by the physical therapist. After this inpatient period, the revalidation is continued on an outpatient basis. In the second protocol the patient is operated in an outpatient setting followed by outpatient revalidation for the moment of operation.

Study burden and risks

Low burden associated with participation. There will be no extra (outpatient) controls other than normal for this operation (2 weeks, 6 weeks, 3 months, 6 months and one year postoperative). During each outpatient control questionnaires will be used to assess the progress of the patient. This will take approximately 10 minutes extra.

In the literature reports are made of the same risks for inpatient and outpatient operated and revalidated patients.

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

Patient with functional complaints of a ruptured anterior cruciate ligament. Able to give informed consent and able to fill in the questionnaires.

Exclusion criteria

open epiphysis of proximal tibia or distal femur

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2009
Enrollment:	46

Type:	Actual

Ethics review

Approved WMO Date:	12-11-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	18-01-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL22881.094.08