Cost-effectiveness of two treatment strategies of an anterior cruciate ligament rupture. A randomized clinical study.

Published: 25-10-2010
Last updated: 15-05-2024

To assess whether there is a clinical relevant effect (and cost-effectiveness) in change in International Knee Documentation Committee* questionnaire over a period of 24 months of an early surgical intervention versus a more conservative management...

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

Summary

ID

NL-OMON41488

Source
ToetsingOnline

Brief title
Cost-effectiveness anterior cruciate ligament rupture treatment

Condition

- Tendon, ligament and cartilage disorders

Synonym
anterior cruciate ligament rupture; insufficient ACL

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: anterior cruciate ligament rupture, Cost-effectiveness, treatment, trial

Outcome measures

Primary outcome

a difference in change in International Knee Documentation Committee* (IKDC) questionnaire (subjective form) after 24 months.

Secondary outcome

difference in scores after 3, 6, 9, 12 and 24 months of IKDC (objective form), KOOS, Lysholm, Tegner, pain severity (VAS), objective instability (KT-1000, Lachman and pivot shift test), satisfaction with treatment, and quality of life (EQ5D). Besides, differences in medical consumption, adverse events (menisci lesions, complications, and re-interventions), absence from work or decreased productivity at paid and unpaid work, and patient costs (PRODISQ, productivity and Disease Questionnaire), to be able to do cost-effectiveness analysis will be assessed.

Study description

Background summary

A rupture of the anterior cruciate ligament (ACL) is a common sports related injury. Significant controversy exists regarding the management of the ACL insufficient knee. Usual care in the Netherlands varies between two widely used strategies, namely; early surgical intervention or a more conservative strategy. Both strategies are financially compensated by the health insurance in the Netherlands.Till date there are no studies investigating the cost-effectiveness of different management strategies of ACL ruptures.

Study objective

To assess whether there is a clinical relevant effect (and cost-effectiveness) in change in International Knee Documentation Committee* questionnaire over a period of 24 months of an early surgical intervention versus a more conservative management of patients with a complete ACL rupture.

Study design

Open-labeled randomized clinical trial.

Intervention

Patients will be randomized in a) *early surgery group* or b) *more conservative management group*. In group a): ACL reconstruction will be performed within 4-6 weeks after inclusion study, followed by an exercise program (standardized protocol) for 9 months. In group b): the primary treatment option is rehabilitation training for 3-4 months followed by assessment of knee function and quality of life. If repeated episodes of giving way in spite of rehabilitation occurs or the patient is not satisfied for any reason, a late reconstruction can be performed (delayed surgery).

Study burden and risks

There is no direct benefit from participation or group relateness. The burden is primarily time (questionnaires).

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

an acute (within 2 months of initial trauma) complete primary ACL rupture (confirmed by MRI, or arthroscopy); age of 18-65 years, and willing to be randomized.

Exclusion criteria

ACL rupture of the contralateral knee, presence of disorder(s) that affects the activity level of the lower limb, dislocated bucket handle lesion of the meniscus with an extension deficit, or insufficient command of the Dutch language, spoken and/or written.

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:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	188
Type:	Actual

Ethics review

Approved WMO Date:	25-10-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2015
Application type:	Amendment
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

ID: 26654
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33702.078.10
OMON	NL-OMON26654