

Should a traumatic meniscal tear be resected? An RCT

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To evaluate the cost-effectiveness of arthroscopic partial meniscectomy compared to non-operative treatment strategy. The hypothesis is that an arthroscopic partial meniscectomy is a cost-effective intervention to treat patients with clinical...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41304

Source

ToetsingOnline

Brief title

Should a traumatic meniscal tear be resected?

Condition

- Joint disorders

Synonym

meniscal tear; meniscal rupture

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: meniscal tear, meniscectomy, non-operative treatment, RCT

Outcome measures

Primary outcome

Difference in clinical outcome measured with International Knee Documentation Committee questionnaire and information for cost-effectiveness analysis will be assessed over 2 years.

Secondary outcome

difference in scores of KOOS, WOMET, work- and sports load, NRS, satisfaction, and EQ5D. Histology of resected meniscal tissue.

Study description

Background summary

Arthroscopic partial meniscectomy is the most popular intervention under orthopaedic surgeons to treat patients with meniscal tears. However, cost-effectiveness of this procedure is seriously questioned. Especially, in case of a traumatic meniscal tear without locking complaints evidence is lacking whether an arthroscopic intervention is the most optimal treatment.

Study objective

To evaluate the cost-effectiveness of arthroscopic partial meniscectomy compared to non-operative treatment strategy. The hypothesis is that an arthroscopic partial meniscectomy is a cost-effective intervention to treat patients with clinical complaints of the knee because of a traumatic meniscal tear (superiority study).

Study design

Open-labeled randomized clinical trial.

Intervention

Patients will be randomized in a) arthroscopic partial meniscectomy; or in b) non-operative treatment strategy. In group a): arthroscopic treatment will be performed, followed by an exercise program if indicated according to Dutch guidelines of physical therapists and orthopedic surgeons. In group b): according to the Dutch guideline for General Practitioners advice, exercise therapy (standardized program), and pain medication will be provided.

Study burden and risks

The burden is primarily time (visit of outpatient clinic, and to fill in questionnaires). There is no direct benefit from participation or group relatedness.

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

a history of trauma moment after which current complaints are initiated; age of 18-45 years; and presence of a meniscal tear grade 3 assessed on MRI.

Exclusion criteria

locking complaints knee; reparable meniscal tear (based on MRI); rupture of anterior or posterior cruciate ligament; knee OA; disabling co-morbidity; or insufficient command of Dutch or English language.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-08-2014
Enrollment:	152
Type:	Actual

Ethics review

Approved WMO	
Date:	04-03-2014
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	20-02-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	17-08-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	10-12-2015
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: 28647

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL46822.078.13