A Study of Traumatic meniscal tears: Arthroscopic Resection vs Rehabilitation

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28647

Source
Nationaal Trial Register

Brief title
STARR-trial

Health condition

-traumatic meniscal tear
-meniscectomy
-physical therapy
-cost-effectiveness

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Clinical relevant difference in International Knee Documentation Committee (IKDC) questionnaire

Secondary outcome

Difference in:

- Knee injury and Osteoarthritis Outcome Score (KOOS)

- Western Ontario Meniscal Evaluation Tool (WOMET)

- Number Rating Scale for knee pain (NRS)

- Work- and sportsload

- Satisfaction

- EQ5D

- Pain medication

- Side effects

Study description

Background summary

Rationale: 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.

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.

Study population: Patients are eligible in the age of 18-45 years consulting an orthopedic surgeon with a history of trauma moment after which current signs and symptoms of a meniscal tear are initiated.

Intervention (if applicable): 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.

Main study parameters/endpoints: Difference in clinical outcome measured with International Knee Documentation Committee questionnaire and information for costeffectiveness
analysis will be assessed over 2 years.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden is primarily time (visit of outpatient clinic, and to fill in questionnaires). There is no direct benefit from participation or group relatedness.

Arthroscopic meniscectomy and non-surgical treatment are both options in the standard care of active patients, with complaints of a traumatic meniscal tear.

Study objective

An arthroscopic partial meniscectomy is a cost-effective intervention to treat patients with clinical complaints of the knee because of a traumatic meniscal tear.

Study design

3, 6, 9, 12 and 24 months

Intervention

Physical therapy

Arthroscopic partial meniscectomy

Contacts

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Eligibility criteria

Inclusion criteria

-Age of 18-45 years

-Presence of a meniscal tear grade 3 assessed on MRI

-History of trauma

Exclusion criteria

-Locking complaints of the knee

-Reparable meniscal tear (based on MRI)

-Rupture of anterior or posterior cruciate ligament

-Knee osteoarthritis

-Disabling co-morbidity

-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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-08-2014
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41304
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4380
NTR-old	NTR4511
CCMO	NL46822.078.13
OMON	NL-OMON41304

Study results

Summary results

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