A Study of Traumatic meniscal tears: Arthroscopic Resection vs Rehabilitation

Gepubliceerd: 14-04-2014 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28647

Bron
NTR

Verkorte titel
STARR-trial

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3, 6, 9, 12 and 24 months

Onderzoeksproduct en/of interventie

Physical therapy

Arthroscopic partial meniscectomy

Contactpersonen

Publiek

Postbus 2040, 3000 AD Rotterdam
M. Reijman
Wytemaweg 80, 3015 CN Rotterdam, kamer HS-104
Rotterdam
The Netherlands
010 7033642

Wetenschappelijk

Postbus 2040, 3000 AD Rotterdam
M. Reijman
Wytemaweg 80, 3015 CN Rotterdam, kamer HS-104
Rotterdam
The Netherlands
010 7033642

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Age of 18-45 years

-Presence of a meniscal tear grade 3 assessed on MRI

-History of trauma

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	07-08-2014
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	14-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41304
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

-