The effect of Hoffa*s fat pad resection in total knee arthroplasty on functionality and pain: a double blind, randomized clinical trial

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

Summary

ID

NL-OMON44041

Source
ToetsingOnline

Brief title
HOPE-study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Anterior knee pain, Hoffa's disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Stichting ALK-RESORT

Intervention

Keyword: Anterior knee pain, Hoffa's fat pad resection, Knee function, Total knee arthroplasty

Outcome measures

Primary outcome

Range of motion at 6 weeks and 3 and 12 months. Gait parameters and preferred

walking speed at 3 and 12 months

Secondary outcome

VAS anterior knee pain score 1 week diary at 6 weeks and 3 and 12 months

KOOS and Kujala score at 6 weeks and 3 and 12 months

Complications and adverse events

Study description

Background summary

Hoffa*s fat pad has been associated with anterior knee pain after total knee arthroplasty. Furthermore, fibrosis of Hoffa*s fat pad due to the incision technique is associated with a decreased range of motion. It*s resection is reported to result in less pain after surgery.

Study objective

The main objective of this study is to test if resection of Hoffa*s fat pad in total knee arthroplasty leads to a greater range of motion and if resection leads to a faster recovery of normal walking gait and preferred walking speed post operatively and at follow-up. Secondary Objectives are to see if, as a result of resection of Hoffa*s fat pad patients have less anterior knee pain, a higher KOOS and Kujala score and better patient satisfaction. Furthermore, we shall assess if resection leads to a higher risk of adverse events due to this

procedure.

Study design

Clinical randomised controlled double blind trial.

Intervention

One group will undergo Hoffa*s fat pad resection and one group will not, during implantation of a total knee prosthesis.

Study burden and risks

The risk associated with participation in this study is considered minimal. Hoffa*s fat pad is often resected to gain better exposure and no adverse events have been reported after this procedure. The treatment and peri-operative protocol will be the standard Joint-Care like protocol of the Medical Centre Alkmaar and will be the same for all patients. The extra burden of participating in this study will be one extra follow-up visit at 3 months post operatively and the filling out of the KOOS and Kujala questionnaire at follow-up visits. Furthermore, all patients shall undergo a 50 meter walking registration which is not in the normal clinical protocol.

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

- Patients who are planned to undergo a primary total knee arthroplasty in the Joint-Care program of the Medical Centre Alkmaar.
- Age between 30 and 80 years
- Patients with ASA Physical Status I & II

Exclusion criteria

- Patients with another prosthesis in either one of the lower extremities
- Patients diagnosed with rheumatoid arthritis
- Patients who suffer from insulin dependant diabetes
- Patients who lack understanding of the Dutch language
- Patients who are treated for or diagnosed with neurological or muscle disorders which make assessment of pain and gait not possible

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL39455.094.12