The clinical outcome after unicompartmental knee arthroplasty compared with total knee arthroplasty and the possible relationship with preoperative arthroscopic chondropathy

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1. Is there a difference in clinical and/or functional outcome between patients older than 60 years undergoing unicompartmental or total knee arthroplasty.2. Is there a relationship between the degree and location of preoperative arthroscopic...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30676

Source
ToetsingOnline

Brief title
TACTIC-study

Condition

- Joint disorders

Synonym
joint wear, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: de maatschappen orthopaedie van de betreffende ziekenhuizen en nog aan te schrijven fondsen.

Intervention

Keyword: arthroplasty, knee, osteoarthritis, replacement

Outcome measures

Primary outcome

WOMAC-score

Secondary outcome

1.KSS, UCLA activity and SF-36-score

2.Complications, revisions

3.Postoperative flexion of the operated knee

4.Radiographical analysis

5.Hospital- and recoveryperiod

6.Bloodloss (Hb pre- en postoperative, peroperative bloodloss, transfusions)

Study description

Background summary

Patients with predominantly medial knee osteoarthritis can be treated with unicompartmental or total knee arthroplasty. Which one of the two should have preference in patients suitable for unicompartmental knee arthroplasty is unclear.
The absence of osteoarthritis in the lateral knee compartment as seen on X-rays is an important factor for succesful unicompartmental knee arthroplasty. Not all osteoarthritis can be seen on X-rays, so it could be that unicompartmental knee arthroplasty is performed in "unsuitable" patients.

Study objective

1. Is there a difference in clinical and/or functional outcome between patients older than 60 years undergoing unicompartmental or total knee arthroplasty.
2. Is there a relationship between the degree and location of preoperative arthroscopic chondropathy and the functional outcome after unicompartmental knee arthroplasty.

Study design

This is a double blind, multicenter, randomized controlled trial (RCT)

Intervention

Patients will be classified/randomized into one of two groups: combined arthroscopy with unicompartmental knee arthroplasty OR combined arthroscopy with total knee arthroplasty. Blinding is done by utilising a straight paramedian medial incision through which both UKA and TKA can be adequatly performed. The initial incision length is 25 cm for TKA and 10 cm for UKA. The 10 cm incision in UKA is superficially extended (on the skin, both proximal and distal), when closing the wound, to the total length of 25 cm necessary for blinding.

Study burden and risks

The total time-burden is about 2,5 hours. Pre- and postoperative laboratory samples and extra X-rays are taken. Complications associated with knee arthroplasty are thrombosis, infection, excessive blood loss and delayed wound healing. The arthroscopy in combination with knee arthroplasty does not cause (in our opinion) additional complications during or after surgery. However, it does lead to an extended surgery-time (10 minutes extra).

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

Osteoarthritis in the medial compartment of the knee.
Patients must have an healthy intact lateral knee compartment, which is determined on X-rays (stage 0 Kellgren and Lawrence- and Ahlback-classification on standard standing AP, lateral and valgusstress knee X-ray).

Exclusion criteria

1. Inflammatory arthropathy (RA, SLE, arthritis psoriatica)
2. Recent septic arthritis
3. Flexion contracture > 10 degrees
4. Preoperative range of motion (ROM) < 90 degrees
5. Angular deformity, fixed or > 15 degrees
6. Deficient anterior cruciate ligament
7. Previous high tibial osteotomy (HTO)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-06-2007
Enrollment:	210
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-05-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL15781.075.07