The clinical outcome after unicompartmental knee arthroplasty (UKA) compared with total knee arthroplasty (TKA)

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Is there a difference in clinical and/or functional outcome between patients older than 60 years undergoing unicompartmental or total knee arthroplasty.

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

Summary

ID

NL-OMON32085

Source
ToetsingOnline

Brief title
NA

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 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 osteoarthritis in the medial compartment of the knee 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.

Study objective

Is there a difference in clinical and/or functional outcome between patients older than 60 years undergoing unicompartmental or total knee arthroplasty.

Study design

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

Intervention

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 1 hour (extra when compared to the normal procedure regarding knee arthroplasty). Pre- and postoperative laboratory samples and X-rays are taken. Complications associated with knee arthroplasty are thrombosis, infection, excessive blood loss and delayed wound healing.

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 with isolated medial compartment osteoarthritis. 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:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	31-01-2008
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	NL20729.075.07