# 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

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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

**Public** Isala Klinieken

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

**Age** Adults (18-64 years)

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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
Туре:	Actual

# **Ethics review**

Approved WMO Date: Application type: Review commission:

31-01-2008 First submission 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 CCMO ID NL20729.075.07