

# Comparison of the uncemented and cemented Oxford unicompartmental knee prosthesis

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The goal of this study is to compare the initial and long term clinical results and survival of the uncemented and cemented Oxford knee prosthesis.- Does the fixation method affect the knee pain?- Are the radiological criteria for success used for...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32282

### Source

ToetsingOnline

### Brief title

Uncemented and cemented UKA

### Condition

- Bone and joint therapeutic procedures

### Synonym

arthritis of the knee, gonartrosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Biomet Nederland BV

**Source(s) of monetary or material Support:** Biomet Nederland BV

## Intervention

**Keyword:** fixation, pain, rapid recovery, Unicompartmental knee prosthesis

## Outcome measures

### Primary outcome

Radiological evaluation, function radiology and survival

### Secondary outcome

Pain and function

## Study description

### Background summary

The unicompartmental knee prosthesis is a proven treatment for patients with medial gonartrosis. Knee prosthesis are traditionally fixed with bone cement. However cementing takes 10-20 minutes additional operation time, waste cement can be left in the joint space and bone cement can in time become brittle. Therefore uncemented fixation methods have been develop which might improve the long term survival.

### Study objective

The goal of this study is to compare the initial and long term clinical results and survival of the uncemented and cemented Oxford knee prosthesis.

- Does the fixation method affect the knee pain?
- Are the radiological criteria for success used for the cemented Oxford prosthesis also true for uncemented fixation.
- Are the middle and long term clinical results of the uncemented Oxford at least as good as for the cemented Oxford?
- Does the uncemented fixation improves the long term survival?

### Study design

Prospective randomized multi center study

### Intervention

Placement of an Oxford hemi knee prosthesis, for the study group the uncemented

version and for the control group the cemented version.

## Study burden and risks

All patients have the standard risk for an unicompartmental knee prosthesis. The clinical results if the uncemented Oxford knee are unknown, however they are expected to be equal to the cemented Oxford. The uncemented Oxford is expected to give a better recovery and longer survival, however they might give early loosening because of insufficient early fixation. The patient will obtain the traditional rehabilitation protocol, during the standard outpatient visits additional questionnaires concerning function and pain will be taken.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Gonartrosis of the knee isolated to anteromedial side
- Both cruciate ligaments must be intact.
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## Exclusion criteria

- Infection
- no informed consent

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Will not start
Start date (anticipated):	01-09-2008
Enrollment:	80
Type:	Anticipated

### Medical products/devices used

Generic name:	knee prosthesis
Registration:	Yes - CE intended use

## Ethics review

Approved WMO

Date: 15-09-2008

Application type: First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

## 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	NL21641.096.08