Patient Blinded Randomized Clinical Trial comparing two types of mobile bearing unicondylar knee replacement

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To assess non inferiority of a Multi Radius design (ACS® unicondylar) compared to a Single Radius design Unicondylar knee implant (Oxford) on clinical outcome using the Oxford Knee Score.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40703

Source
ToetsingOnline

Brief title
Uni-Trial

Condition

- Bone and joint therapeutic procedures

Synonym
Osteoarthritis, Worn knee

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Implantcast

Intervention

Keyword: Hemi-knee arthroplasty, Knee, Osteoarthritis

Outcome measures

Primary outcome

Our main study endpoint is the Oxford Knee Score. A knee specific questionnaire specifically designed to measure outcome in knee arthroplasty patients. This score was chosen since most Partial Knee studies use this outcome, therefore our study can be compared with the other Partial Knee papers.

Secondary outcome

• To compare the overall QoL in patients with a Single Radius design Unicondylar knee implant (Oxford Partial Knee ®) to patients with a Multi Radius design (ACS® unicondylar). The Quality of life will be measured by using standardized questionnaires being: NRS for pain, EQ5D and a KOOS-PS.

• To monitor and compare the revisions (survival) rate of both groups. All revisions (septic and aseptic) and second surgery for other reasons will be included in the survival analysis.

• Level of resection needed for implantation.

Study description

Background summary

In the last decades unicondylar knee arthroplasty has become widely accepted as a valid option in the treatment for unicondylar osteoarthritis. Over these decades several design options are altered and the best documented is the Oxford® unicondylar design which has a mobile bearing and single radius design. In Total knee arthroplasty the multi radius design is proven as an excellent solution. This study is designed to show the non-inferiority of the ACS®

unicondylar knee arthroplasty, which is a mobile bearing with a multi radius design, compared to a Single Radius design Unicondylar knee implant (Oxford).

Study objective

To assess non inferiority of a Multi Radius design (ACS® unicondylar) compared to a Single Radius design Unicondylar knee implant (Oxford) on clinical outcome using the Oxford Knee Score.

Study design

The study design is a prospective patient blinded randomized controlled study comparing a Single Radius design Unicondylar knee implant (Oxford) with a Multi Radius design (ACS® unicondylar) in terms of clinical outcome.

Intervention

Unicondylar knee arthroplasty with either the Oxford® unicondylar knee arthroplasty or the ACS ® unicondylar knee arthroplasty.

Study burden and risks

All patient will be seen at regular follow up intervals identical to the normal unicondylar knee arthroplasty protocol. At these visits patients will be asked to fill out a questionnaire.
All patients will be treated according to standard UKA protocol, with an implant that is available on the market and has a CE marking. Bearing this in mind we judge the study as safe.

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

• Age > 18
• BMI < 40
• Medial Unicondylar symptomatic OA of a knee joint
• Able to provide informed consent

Exclusion criteria

• Co-morbidity influencing the outcome of the implant.
• Hypersensetivity to metals.
• Not being able to fill in the Dutch Questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2015
Enrollment:	236
Type:	Actual

Ethics review

Approved WMO

Date:	31-10-2014
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29323
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50651.048.14
OMON	NL-OMON29323