Uncemented tibial component fixation in total knee replacement using porous titanium.
A Randomised RSA Study

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The aim of this study is to compare the early post-operative migration as measured by Roentgen Stereophotogrammetric Analysis (RSA) of the cemented tibial component with the uncemented porous coated tibia component.

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

Summary

ID

NL-OMON36423

Source
ToetsingOnline

Brief title
Uncemented tibia fixation in total knee replacement

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
cartilage damage, Knee arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Biomet Nederland B.V.

Intervention

Keyword: Porous titanium, Roentgen Stereophotogrammetric Analysis (RSA), Total knee replacement, Uncemented tibia fixation

Outcome measures

Primary outcome

Migration parameters:

- Maximum total point migration (MTPM)

- Maximum subsidence

- Maximum lift-off

Secondary outcome

Clinical evaluation:

- IKSS (International Knee Society Score)39

- SF36 (Short Form (36) health survey)40

- KOOS (Knee injury and Osteoarthritis Outcome Score)41

- Range of motion of the knee

Study description

Background summary

The most important failure mechanism of TKA, apart from polyethylene wear, is aseptic loosening of the implant. Failure risk is mainly determined by the quality of fixation and mechanical characteristics of the prosthesis. In literature, the issue whether or not to use cement in TKA is not yet resolved. Cement is reported to cause damage, either by its toxicity or due to the heat used for polymerisation. Finally, cement might leak and destruct the

polyethylene layer of the prosthesis. Cementless prostheses are designed to allow osseointegration in order to provide a stronger and longer lasting fixation and a more physiological load transfer between the bone and the prosthesis.

Study objective

The aim of this study is to compare the early post-operative migration as measured by Roentgen Stereophotogrammetric Analysis (RSA) of the cemented tibial component with the uncemented porous coated tibia component.

Study design

This clinical study is a prospective randomised RSA-controlled non-inferiority trial. 42 patients will be included in the AMC, 21 in the treatment (uncemented tibia component) and 21 in the control (cemented tibia component) group.

Intervention

The patient will receive either the cemented tibial component (control group) or the uncemented porous coated tibial component (intervention group)

Study burden and risks

The effective radiation dose per RSA-radiograph is 3µSv. The additional annual radiation dose is negligible if the natural exposure of 2 mSv is considered. The effective radiation dose of a standard knee radiograph is 0,01 mSv.

Theoretically, the use of tantalum markers is associated with a slightly elevated risk of infection. However, in literature no mention of this elevated risk can be found. Other potential risks are risks associated with normal total knee replacements such as infection, migration, bone loss, pain, loosening of components, tromboembolic complications and risks involving anaesthesia.

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 diagnosed with osteoarthritis or rheumatoid arthritis of the knee requiring primary total knee arthroplasty
•Patients capable of giving Informed Consent and expressing willingness to comply with the post-operative follow-up program
•Patients having no major deformities, i.e. sagittal and coronal deformities are less than 15 degrees

Exclusion criteria

•Patients requiring revision arthroplasty
•Patients unable or unwilling to sign the Patient Informed Consent specific to this study
•Patients with osteoporosis of the tibial plateau
•Patients with functional impairment of any other lower extremity joint besides the operated knee
•Patients having a flexion contracture of 15° and more
•Patients having a varus or valgus contracture of 15° and more
•Patients having insufficient understanding of Dutch language to participate
•Patients incompetent to fill in the clinical scores

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:	Pending
Start date (anticipated):	01-07-2011
Enrollment:	42
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL34096.018.10