# The effect of Refobacin and Palacos bone cement on fixation of total hip prosthesis (THP): A clinical RSA-study on a force enclosed stem.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

# Summary

### ID

NL-OMON30670

Source ToetsingOnline

**Brief title** Effect of 2 bone cements on fixation of THP

# Condition

Bone and joint therapeutic procedures

**Synonym** Prosthesis fixation / loosening

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Leids Universitair Medisch Centrum

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#### Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

Keyword: bone cements, hip prosthesis, loosening

### **Outcome measures**

#### **Primary outcome**

Pre-treatment evaluation will consist of clinical assessment, and medical

history, functional evaluation (using different score forms) and by

radiographic evaluation. After surgery evaluation will be performed on

different intervals using measurements of RSA and functional evaluation (e.g.

pain, work/activity level).

#### Secondary outcome

None

# **Study description**

#### **Background summary**

Palacos that is marketed since 1985, has been found with very good clinical results concerning survival rate of cemented prostheses (Havelin et al., 1995, Harper). Refobacin contains the same ingredients as Palacos, however in different proportions and has gained CE-approval. However clinical studies evaluating the two bone cements are lacking.

#### **Study objective**

The objective of this study is to assess the difference in micromotion of the Exeter hip prosthesis, using two different bone cements. We hypothesise that the newly marketed bone cement Refobacin- gentamycine has the same in vivo properties as the Palacos bone cement. These properties are evaluated by micromotion patterns of the hip stem and cup of the prosthesis as measured by RSA (radiostereometry).

#### Study design

A prospective randomised blinded study will be performed. The study will be conducted in one hospital in The Netherlands and patients will be followed until death or when the prosthesis is removed. Patients will be randomized in one of the two bone cement groups (either Palacos or Refobacin, both with gentamycine, and will be followed on different intervals. For follow-up Roentgen Stereophotogrammetric Analysis is used in combination with regular clinical evaluation.

#### Study burden and risks

Patients are not at risk to receive high doses of radiation and there is no enlarged risk for infections, migration, bone loss and pain associated. Future benefits for the patients are that this study will give more insight in the understanding of the fixating of prostheses, resulting in better designs and techniques of total hip prosthesis (Exeter hip).

# Contacts

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Patients with primary and secondary osteoarthritis who need a total hip prosthesis; Patients capable of giving informed consent and expressing a willingness to comply with the post-operative review program

### **Exclusion criteria**

Patients requiring revision arthroplasty; Patients with primairy bone disease The patient is unable or unwilling to sign the Patient Informed Consent (PIC) specific to this study

# Study design

### Design

Study phase:	4	
Study type:	Observational non invasive	
Intervention model:	Parallel	
Allocation:	Randomized controlled trial	
Masking:	Double blinded (masking used)	
Control:	Active	
Primary purpose:	Treatment	

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	50
Туре:	Anticipated

# **Ethics review**

Approved WMO Application type: Review commission:

First submission METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

# **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** NL13748.058.07