The effect of Refobacin and Palacos bone cement on fixation of total hip prosthesis (THP): A Clinical RSA-Study of a form enclosed stem

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The objective of this study is to assess the difference in micromotion of the Stanmore hip prosthesis (form enclosed), using two different bone cements. We hypothesise that the newly marketed bone cement Refobacin- gentamycine has the same in vivo...

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

Summary

ID

NL-OMON30760

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

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. 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 Stanmore hip prosthesis (form enclosed), 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 (Stanmore hip).

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 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:	Recruiting
Start date (anticipated):	19-11-2007
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL16073.058.07