Comparison of the fixation and stability of two bone substitutes: Pro Osteon and Calcibon by revision of the acetabulum prosthesis with RSA

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Which of the products, Pro Osteon or Calcibon gives the best stability and fixation of the acetabulum prosthesis by revision procedures.

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

Summary

ID

NL-OMON29776

Source
ToetsingOnline

Brief title
Comparison of Pro Osteon and Calcibon during revision THA

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
revision total hip; bone defect

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: Biomet Nederland BV zal de extra kosten voor haar rekening nemen,Ortomed

Intervention

Keyword: Calcibon, ProOsteon, revision acetabulum, RSA

Outcome measures

Primary outcome

Migration of the prosthesis

Secondary outcome

Pain, function and patient satisfaction

Study description

Background summary

A huge complication during revision surgery of an acetabulum cup prosthesis is insufficient bone stock. The insufficient bone stock causes an insufficient fixation and thereby early loosening of the new prosthesis. Several materials have been proposed to replace the missing bone. Two of these materials are Pro-osteon and Calcibon. Pro-Osteon is a hydroxyapitie bone graft with the same strength and healing proportions as normal bone and is normally used in this hospital. Calcibon is a synthetic bio resorbable calcium phosphate base bone substitute. Which of these materials give the best clinical results is unknown.

Study objective

Which of the products, Pro Osteon or Calcibon gives the best stability and fixation of the acetabulum prosthesis by revision procedures.

Study design

Prospective randomized study

Intervention

All patients will obtain a cemented Stanmore acetabulum cup prosthesis. By 10 patients the bone defects will be filled with Pro-Osteon and by 10 patients the bone deficits will be filled with Calcibon. In the bone and on the prosthesis

RSA markers will be placed. Postoperative at 1 and 6 weeks and 4, 12 and 24 month, stereo-radiographs will be made to measure the migration of the prosthesis with RSA.

Study burden and risks

The risks for the participants are the normal risks for revision acetabulum surgery. Added burdens for the patient are 5 stereo roentgen photos and 5 questionnaires concerning the pain and function of 20 minutes each.

Contacts

Public
Weteinde Ziekenhuis

Lijnbaan 32
2512 VA Den Haag
NL
Scientific
Weteinde Ziekenhuis

Lijnbaan 32
2512 VA Den Haag
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Needing revision surgery for a loose acetabulum component
Age above 18 years old
Insufficient bone stock for fixation

Exclusion criteria

Infection
per-operative insufficient bone stock

Study design

Design

Study phase:	4
Study type:	Interventional
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):	01-06-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-08-2006
Application type:	First submission
Review commission:	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	ID
CCMO	NL11402.098.06