Long term follow-up and survival of the uncemented Omnifit femoral stem after acetabular component revision

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to analyse patient functional outcome (objectively and subjectively), radiographic results of both acetabular and femoral component, and rate of complications after revision of the acetabular component

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33108

Source
ToetsingOnline

Brief title
Survival of the uncemented Omnifit femoral stem

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
survival, total hipprosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: Femoral, Omnifit, Revision, Uncemented

Outcome measures

Primary outcome

functional outcome using scoring systems (Oxford Hip score, HOOS, VAS for pain/

satisfaction and experienced recovery)

Secondary outcome

radiographic results: osteolysis using Gruen (femoral stem) and DeLee-Charnley

(acetabular component) zonal system, amount of migration and collapse of both

components

complications: secondary revisions, infections, dislocations and death

Study description

Background summary

in the past the uncemented Omnifit (Osteonics Corporation, Allendale, New Jersey, USA) total hip prosthesis has been used in treating osteoarthritis of the hip. Previously, unsatisfactory results with the uncemented acetabular component have been reported. Frequently, the acetabular component had to be revised due to loosening from polyethylene disease and severe osteolysis. However, the femoral component was revised less frequently. To date, only few studies have been published on the survival of the Omnifit total hip prosthesis with a maximum follow-up of 20 years and a reported excellent survivorship of the femoral stem of nearly 100%. However, functional outcome in patients who had a revision operation has not been described

Study objective

to analyse patient functional outcome (objectively and subjectively), radiographic results of both acetabular and femoral component, and rate of

complications after revision of the acetabular component

Study design

follow-up study

Study burden and risks

although an extra radiographic exam will be performed to analyse radiographic results no extra risks are to be expected as those standard for regular follow-up in the outpatient clinic

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 who had a revision operation for loosening of the acetabular component of the uncemented hydroxy-apatite coated Omnifit total hip prosthesis

Exclusion criteria

-

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL27102.008.09