Long-Term Multi-center Evaluation of E-Poly* and Regenerex* Cementless Acetabular Components: Clinical and Radiographic Outcomes

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

Summary

ID

NL-OMON43925

Source
ToetsingOnline

Brief title
Regenerex

Condition

- Joint disorders

Synonym
Osteoarthritis, wear

Research involving
Human

Sponsors and support

Primary sponsor: Biomet Nederland BV

Source(s) of monetary or material Support: Massachusetts General Hospital en Biomet Inc

Intervention

Keyword: Survival, total hip replacement, Uncemented, Wear

Outcome measures

Primary outcome

Wear measurements with X rays and clinical results measured with

questionnaires

Secondary outcome

Survival

Study description

Background summary

The main causes for a revision of a hip prosthesis are loosening of the acetabulum or wear of the liner. To reduce the loosening and wear rates, two new materials have been developed. Regenerex* is a metal with a titanium porous surface which induces early bone ingrowths and thereby inhibits osteolysis and loosening. E-poly* is a polymer containing vitamin E as an anti-oxidant, which makes it possible to have a higher long term wear resistance as conventional polymers. Both materials have shown good laboratories results and are therefore accepted on the US and European market. However, long term clinical studies are lacking

Study objective

The purposes of this long-term mutli-center study are:
- To compare the long-term (10-year) radiographic and clinical outcomes of new E-Poly* liner in primary total hip arthroplasty with the conventional ArcomXL® polyethylene liner.
- To compare the long-term (10-year) radiographic and clinical outcomes of the Regenerex Ringloc +* acetabular component having a titanium porous surface with the conventional plasma sprayed acetabular coating.

Study design

Multi center, international study with 1000 patients divided into 4 groups;
1) E-Poly* liner in a titanium plasma sprayed RingLoc® shell,
2) ArcomXL® polyethylene liner in a titanium plasma sprayed RingLoc® shell,
3) Regenerex Ringloc +* shell with E-Poly* liner
4) Regenerex Ringloc +* shell with ArcomXL® polyethylene liner.
Because all groups demand special surgical instruments, prosthesis and techniques, each hospital is randomized into 1 group. Each group contains 5 hospitals placing 50 prosthesis each. The Scheper hospital in Emmen is randomized in group 4.

Intervention

An uncemented total hip prosthesis with an Taperloc stem, Regenerex Ringloc +* shell and ArcomXL® polyethylene liner

Study burden and risks

Risks associated with hip replacements. Seven outpatient visits with X-rays and questionnaires (duration of 30 minutes), all of them are regular visits.

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

1. Male or female
2. 20 to 75 years of age
3. Subjects requiring primary total hip replacement
4. Subjects with diagnosis of osteoarthritis, or traumatic arthritis
5. Subjects with the appropriate bone stock to accept an acetabular component with a 32mm inner diameter.
6. Subjects who demonstrate the ability to return for follow-up for the next ten years.

Exclusion criteria

1. Subjects with limited life span
2. Subjects with difficulty in comprehending study protocol for any reason.
3. Subjects with inflammatory disease, previous infection or those requiring revision hip surgery.
4. Subjects with avascular necrosis.
5. Subjects whose bony structures are so small that a femoral head less than 32mm in diameter must be used.
6. Subjects whose bony structure deviates substantially from the general norm sufficiently to require non-standard techniques and non-standard implants. Specific examples of these are total dislocation of the hip, severe coxa vera deformity, severe forms of multiple epiphyseal dysplasia
7. Subjects with complex disease entities which significantly increase the risks of the surgery such as any major platelet abnormality, hematological disorder, positive for HIV or any other major medical complication which substantially reduces longevity.
8. Female subjects that are pregnant or who may suspect they are pregnant or who plan to become pregnant while participating in this study.

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2008
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
ClinicalTrials.gov	NCT00545285
CCMO	NL21615.056.08