A model-based RSA Randomized Control Trial to evaluate the stability of the cementless Taperloc hip stem in four different treatment groups.

Published: 12-02-2014
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Evaluate the safety and effectiveness of four cementless Taperloc versions: Taperloc Complete Reduced Distal and Taperloc Legacy Full Profile Reduced Distal compared to Taperloc Complete Full Profile and Taperloc Legacy Full Profile in primary THA.

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

Summary

ID

NL-OMON45008

Source
ToetsingOnline

Brief title
TAPHIP

Condition

- Joint disorders

Synonym
joint wear, osteoarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum

Source(s) of monetary or material Support: BioMet,Biomet GSCC BV

Intervention

Keyword: hip prosthesis, model-based RSA, Taperloc

Outcome measures

Primary outcome

Primary endpoint is implant stability (measured with Model-based RSA) at 2 years follow-up.

Secondary outcome

Secondary endpoints are implant stability and development (early or late ingrowth) during the pre-defined follow-up periods, standard radiographic parameters which include qualitative femoral and acetabular findings as well as position of the stem and cup, clinical outcomes measured with patient reported outcomes. Other clinical data about the procedure intraoperative/surgical data, survivorship and adverse events will be routinely monitored.

Study description

Background summary

A model-based RSA Randomized Control Trial to evaluate the stability of the cementless Taperloc Complete compared to cementless Taperloc Legacy in primary THA.

Study objective

Evaluate the safety and effectiveness of four cementless Taperloc versions: Taperloc Complete Reduced Distal and Taperloc Legacy Full Profile Reduced Distal compared to Taperloc Complete Full Profile and Taperloc Legacy Full Profile in primary THA.

Study design

Prospective 4 Arm Randomized Control Trial. All included patients will be assessed preoperative and directly postoperative. Follow-up will take place at 6 weeks, 3 months, 1, 2, 5, 7 and 10 years postoperatively. Assuming the enrolment will be completed in two years total study duration will be 12 years.

Intervention

All patients will receive a total hip prosthesis because of their invalidity and health problems which will be monitored by model-based RSA analysis. Four different hip prostheses will be used.

Study burden and risks

Subjects participating in the study have the same risks and benefits when not participating in the study. The Taperloc is clinically successfully used for thirty years. Follow-up times are standard protocol evaluations of prosthesis. During follow-up times adapted radiological evaluation (model-based RSA) and the tantalum beads inserted during surgery, which are necessary to perform this type of radiological evaluation, are additional for study participants.

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

- Noninflammatory degenerative joint disease including osteoarthritis, avascular necrosis and rheumatoid arthritis.
- Correction of functional deformity.
Additional inclusion criteria include:
- Male or female
- > 18 and <= 75 years of age
- Subjects willing to return for follow-up evaluations that cost a bit more time because of RSA evaluation
- Subjects able to read and understand Dutch language.

Exclusion criteria

- Any active infection, sepsis or osteomyelitis; standard contraindications for elective surgery
- Uncooperative patient or patient with neurologic disorders who are incapable of following directions
- Osteoporosis or osteomalacia as assessed during preoperative planning.
- Metabolic disorders which may impair bone formation
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, which cannot be explained by other comorbidity
- Vascular insufficiency, muscular atrophy or neuromuscular disease.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-06-2014
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	total hip prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-02-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-04-2017
Application type:	Amendment
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	NL45981.098.13