Migration of SL-Plus Standard versus SL-Plus Hydroxyapatite (HA) coated stem: A comparison RSA Study.

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Prove by means of RSA, that HA coating has an advangtage in stability of the uncemented SL-PLUS femoral component in primary total hip arthroplasty.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32075

Source
ToetsingOnline

Brief title
SL-Plus femoral Stem

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Primary osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Smith&Nephew, Inc
Source(s) of monetary or material Support: Smith & Nephew

Intervention

Keyword: Hydroxyapatite coating, Polyethylene wear, Randomized., RSA

Outcome measures

Primary outcome

Migration of femoral component

Secondary outcome

Wear of the polythylene insert of the acetabular component, radiolucent lines

around femoral component, Harris Hip Score and Womac score.

Study description

Background summary

Hydroxyapatite (HA) stimulates bone ongrowth in uncemented hip prostheses, and therefore less radiolucent lines on standard x-rays. But whether or not early migration (2-5 years postoperative) will be less at HA coated SL-PLUS femoral components compared to standard SL-Plus femoral components still is an unanswered question. Longterm clinical results of SL-PLUS femoral omponents are excellent.
RSA is a reliable, frequently used methode to measure early migration (after 2 years) of the protheses in bone.
The objective of this study is to prove by means of RSA, that migration of the HA coated SL-PLUS femoral component might be less compared to the migration of the standard SL-PLUS femoral component.

A second objevctive of the RSA study is to measure polyethylene wear of the acetabular insert, which has been implanted by using navigation to gain an optimal position of the cup in the acetabulum. Within the same study group, a controlled randomized study will be performed to investigate if there is any difference in wear between standard polyethylene and cross linked polyethylene inserts. During hipsimulation studies it appeared that cross linked polyethylene generates less wear particles. A possible disadvantage might be a decrease of visco-elasticity.

Study objective

Prove by means of RSA, that HA coating has an advangtage in stability of the

uncemented SL-PLUS femoral component in primary total hip arthroplasty.

Study design

Randomised, controlled, single blind, monocenter prospective study.

Intervention

Total hip arthroplasty

Study burden and risks

Besides the radiation and extra time for RSA measurements, there will be no extra burden for the patient.

The radiation dose of those extra x-rays per patient during the first 2 years will be 1.8 mSv (=6*0.3mSv). This is comparble with normal background radiation in the Netherlands (2.0 mSv/year)
During the 5th year of the study, the extra radiation dose per patient will be 0.3mSv, much lower than the normal background radiation.

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 osteoarthritis, avascular necrosis, hip dysplasia and requiring arthroplasty
Age 60-75 (inclusive); patients given informed consent
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Exclusion criteria

Patients with proximal femur fracture, infection or prior osteotomy of affected hip joint; patients under treatment with bisphosphonates for osteoporosis; diagnosed Charnley C; requiring cortison medication; with BMI>35; requiring revision arthroplasty;
patients who need bilateral total hip replacements can only participate for one hip.
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Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Start date (anticipated):	01-09-2008
Enrollment:	52
Type:	Anticipated

Medical products/devices used

Generic name:	Total Hip
Registration:	Yes - CE intended use

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20898
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL23524.048.08
OMON	NL-OMON20898