SL-PLUS, FEMORAL STEM. A PROSPECTIVE, RANDOMIZED, SINGLE CENTER, CLINICAL STUDY OF THE SL-PLUS FEMORAL STEM (Standard versus HA coated) IN TOTAL HIP REPLACEMENT

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20898

Source
Nationaal Trial Register

Health condition

hip, prosthesis, stability, Roentgen Stereophotogrammetric Analysis (RSA), stem

Sponsors and support

Primary sponsor: MC Slotervaart
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

RSA migration during the first 5 years of follow up

Secondary outcome

Harris Hip Score

HOOS Pain and ADL domains

Study description

Background summary

An ongoing discussion is whether using a hydroxy-apatite coating enhances the ingrowth and longevity of a femoral stem in total hip arthroplasty. The best way to predict speed of ingrowth and long-term outcome is by performing a radiostereometric analysis study. In order to study the effect of hydroxyapatite (HA) coating on the migration of the SL-PLUS hip stem, a single center RSA, prospective double blind randomized controlled trial is being conducted. The primary objective is to investigate the early migration of the hydroxyapatite (HA)-coated SL-PLUS stem compared to the Standard (non-coated) SL-PLUS stem by means of RSA.

Study objective

The primary objective is the investigation early migration of the SL-PLUS stem measured by means of Roentgen Stereophotogrammetric Analysis (RSA). Migration is assessed with regard to translation (x, y and z direction) and rotation. Early migration will be compared between the HA-coated SL-PLUS stem (Study group) and the standard SL-PLUS stem (control group).
H0: Total migration in the HA-coated group is equal or more compared to the migration in the non-HA coated group.
H1: Total migration in the HA-coated group is less than in the non-HA-group.

Study design

Pre-operative, direct postoperative, 6 weeks, 3 months, 6 months, 12 months, 2 years and 5 years.

Intervention

Total hip arthroplasty with either a standard or a hydroxyapatite coated stem.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with primary osteoarthritis, avascular necrosis, femoral neck fracture, or hip dysplasia

- Patients requiring primary arthroplasty

- Age at time of surgery: 60-75

- Both male and female

- Patients capable of giving informed consent and expressing a willingness to comply with the post-operative review program

Exclusion criteria

- Post-traumatic OA (proximal femur fracture)

- Post-infection in respective joint

- Prior osteotomy of the affected hip

- Patients under treatment for osteoporosis (with bisphosphonate)

- OA patients diagnosed Charnley C

- Patients requiring cortisone medication

- Patients whose body mass index is higher than 35

- Patients already participating in the RSA hip study.

- The individual is unable or unwilling to sign the patient informed consent specific to this study

- Patients requiring revision arthroplasty

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2009
Enrollment:	52
Type:	Actual

Ethics review

Positive opinion

Date:	21-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32075
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5605
NTR-old	NTR5844
CCMO	NL23524.048.08
OMON	NL-OMON32075

Study results

Summary results
N/A