RadioStereometric Analysis of the Plus orthopedics SL-MIA stem and the SL-stem, a randomised controlled trial.

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Objective: non-inferiority in fixation of the SL-PLUS MIA compared to the traditional SL-Plus stem and superiority of the SL-PLUS MIA in terms of bone and muscle preservation and thereby increased patient satisfaction and outcome as measured by PROM...

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

Summary

ID

NL-OMON42137

Source
ToetsingOnline

Brief title
RSA of the SL-MIA Plus and SL-Plus stem, a RCT

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Coxarthrosis, Osteo-arthritis of the hip, painful worn hipjoint

Research involving
Human

Sponsors and support

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

Inc,Stichting Pon

Intervention

Keyword: RadioStereometric Analysis RSA, SL Plus, SL-MIA Plus, Zweymüller

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary endpoint will be implant migration after two years. Migration will be measured by RSA.

Secondary outcome

Secondary endpoints will be bone density alteration measured by DEXA scan, HOOS scores over time, postoperative pain, patient satisfaction, length of hospital stay.

Study description

Background summary

Rationale: The (Zweymüller) SL-Plus stem produced by Plus Orthopedics (Smith & Nephew) has an excellent long term survival of 95% at 15 years with revision for aseptic loosening. However the bulky geometry of the stem impedes minimal invasive surgery. Slight alterations in design has resulted in the SL-PLUS MIA (Minimal Invasive Arthroplasty) which is more suitable for less invasive surgery facilitating in less peroperative bone loss and lesser amount of muscle damage. Primary fixation of the SL-Plus and SL-PLUS MIA is achieved by distal press fit fixation of the stem during implantation. The proximal hydroxyapatite coating of the SL-PLUS MIA stem assists bony ingrowth resulting in secondary stability.

Study objective

Objective: non-inferiority in fixation of the SL-PLUS MIA compared to the traditional SL-Plus stem and superiority of the SL-PLUS MIA in terms of bone and muscle preservation and thereby increased patient satisfaction and outcome as measured by PROM*s.

Study design

Study design: randomised controlled trial

Intervention

Intervention: after informed consent patients are randomised in one of two groups. One group receives the currently used traditional SL-Plus stem and the other group receives the SL-PLUS MIA-stem. Each group will contain 30 patients. A *Hardinge* approach of the hip is used in both groups.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden of participation in this trail will be the specialized RSA X-rays at follow up, clinical follow up with PROM*s and the DEXA scan until 2 years after the total hip arthroplasty. The amount of exposure to radiation will be slightly higher but of no clinical consequence.

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 of the hip with an indication for total hip arthroplasty.
• Age 50 to 80
• ASA 1 and 2
• unilateral coxartrhosis
• Informed consent of patient
• Initial willingness to comply with the post-operative review program

Exclusion criteria

• Ability to comply to the postoperative investigational program
• THA or osteosynthesis on the contra lateral hip (not suitable as reference during DEXA-scan)
• Expectation that the contra lateral hip also needs a THA within a year
• THA because of fracture
• Prior surgery on effected hip
• Revision arthroplasty
• Acute or chronic infections (local or systemic)
• Metabolic diseases of the bone
• Diseases of the muscular, nervous, or vascular systems that seriously will involve the mobility of the patient after a THA
• Femora with structural defects or poor bone quality affecting the stability of the prosthesis
• Any concomitant disease which may endanger the implant*s function
• Patients with rheumatic, renal, hepatic or gastrointestinal disease and patients using medication that interferes with mineral metabolism (i.e. treatment for osteoporosis or long-term steroid therapy).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-08-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL51323.075.14