A prospective randomised Rontgen Stereophotogrammatic Analysis (RSA) study using the uncemented Trident Tritanium acetabular component and the uncemented HA coated Symax hip stem in a single centre.
Assessment of implant migration, bone remodeling and clinical function.

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The goal of this clinical investigation is to assess the early migration and bone remodeling of the Symax hip stem and the Trident HA coated or Trident Tritanium acetabulum component with RSA and 18-F PET CT Also the sensitivity of the RSA...

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

Summary

ID

NL-OMON44926

Source
ToetsingOnline

Brief title
Trident Tritanium and Symax RSA study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
hip osteoarthritis, hip prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Stryker

Intervention

Keyword: hip prosthesis, micromotion, RSA, total hip arthroplasty

Outcome measures

Primary outcome

The primary objective is to determine the prosthetic migration of the uncemented Trident acetabular component (Tritanium or HA coated (controls)) and the uncemented HA coated Symax stem from post-op until 2 years after implantation using the model based RSA technique.

Secondary outcome

The secondary objective of this study is to asses clinical outcome and patient satisfaction in patients implanted with the uncemented Trident acetabular component (Tritanium or HA coated (controls)) and the uncemented HA-coated Symax hip stem from post-op until 2 years after implantation using the Harris Hip Score, Oxford Hip Score, WOMAC and EQ-5D questionnaires at pre-op, 12w, 26w, 52w and 104w.

The tertiary objective of this study is to assess bone remodeling of the uncemented Trident acetabular component (Tritanium or HA coated (controls)) and

the uncemented HA-coated Symax hip stem from post-op until 2 years after implantation using QCT derived from using F18-Fluoride PET (Positron Emission Tomography) in a cohort of 12 consecutive patients (to be exact patients 11-23 in inclusion scheme) at 12, 26, 52 and 104 weeks post-op.

The fourth objective of this study is to determine prosthetic migration and patient satisfaction at 5 years after surgery.
A hip implant that is initially properly fixed to the bone, can show micromovement after some years. This can be a first sign of loosening, resulting in implant failure. So 5 year post-operative evaluation is important to confirm quality and safety of this implant as well as to determine the predictive capacity of RSA in terms of mid- and long term implant survival.

Study description

Background summary

Cementless hip arthroplasty is one of the most successful orthopaedic techniques. Still the survival of hip implants is not indefinite. One of the causes for implant failure in loosening and osteolysis as a consequence of particulate wear and stress shielding. The Symax hip used in this study is designed to optimize stability, fixation and preservation of bone stock, to prevent loosening. By way of measurements of micromotion in the first years after implantation a long term prediction can be made of prosthetic loosening. A very accurate way to measure micromotion is roentgen stereophotogrammetric Aanalysis (RSA). The development to optimalise prosthesis fixation is tsill ongoing. At the moment, in Maastricht, the Trident HA coated acetabulum component is the implant of choice. Th etrident Tritanium acetabulum component does not have a HA coating but instead a porous metal structure that facilitaes bone ingrowth and subsequently leading to component fixation. A second aim of our study is the asssessment of both fixation methods and based on our hypothesis that theTrident Tritanium acetabulum component will have a better fixation compared with the Trident HA coated acetabulum component as measured

by RSA and 18F PET CT.

Study objective

The goal of this clinical investigation is to assess the early migration and bone remodeling of the Symax hip stem and the Trident HA coated or Trident Tritanium acetabulum component with RSA and 18-F PET CT Also the sensitivity of the RSA measurements done at AZm will be assessed . Furthermore, complications, clinical outcome and patient satisfaction will be assessed and clinical function questionnaires filled in by doctors and patients will be evaluated.

Study design

This is a prospective clinical follow up study with an RCT design in a single centre. A group of 50 patients who will receive a Symax hip stem. with also a Trident HA coated acetabulum component or Trident Tritanium acetabulum component.

Intervention

All study patinets willbe implanted with an uncemented Trident HA coated or Trident Tritanium acetabulum component and an uncemented Symax HA coated hip prothesis. To adequately measure RSA a number of tantalum beads (diameter 0.8mm) will be placed in the femoral and pelvic bone which leads to a minimal extension of surgery time. A number of days after surgery and during subsequent follow-up times RSA x-rays will be made for implant migration research. and standard X-rays and 18F PET CT willbe made to evaluate bone remodleing and implant fixation.

Study burden and risks

Tijdens deze studie worden standaard rontgenfoto's, RSA rontgenfoto's en 18-F PET CT scans gemaakt. De stralenbelasting hiervan staat beschreven protocol pagina 11. Verder worden de patienten gevraagd om op vaste tijdstippen een aantal vragenlijstjes in te vullen. Risico's aan dit onderzoek zijn verder niet anders dan de risico's van een totale heupoperatie

During this study standard X-rays, RSA X-rays eand 18-F PET CT scans are made. The radiation exposure is described in the protocol page 11.
The patients are also asked to fill in some questionnaires at regular follow-up visits in the clinic. Further there are no more risks dan the standard risks associated with total hip replacement.

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 aged between 35 and 70 years
Patients requiring uncemented primary THA
Patients with a diagnosis of osteoarthritis, rheumatoid arthritis, avascular necrosis or post-traumatic arthritis

Exclusion criteria

Patients who require a revision of previous implanted THA
Patients with BMI>35
Patients who have had a prior procedure of femoral osteotomy patients with active or suspected infection patients with malignancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2011
Enrollment:	57
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	14-04-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-10-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	19-05-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL33832.068.10