A clinical RSA study using the Symax stem

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The goal of this clinical investigation is to assess the early migration of the Symax stem and the precision of the RSA measurements done at this hospital. Also clinical outcome and patient satisfaction will be assessed.

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

Summary

ID

NL-OMON30594

Source
ToetsingOnline

Brief title
RSA Symax hip

Condition

- Joint disorders

Synonym
hip osteoarthritis, hip prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Stryker Howmedica
Source(s) of monetary or material Support: Stryker

Intervention

Keyword: hipprosthesis, micromotion, RSA

Outcome measures

Primary outcome

The primary study objective is to determine the prosthetic migration of the

Symax stem in the first two years after implantation

Secondary outcome

Secundary objectives are the clinical outcome of these patients and the patient

satisfaction. And also the assessment of the precision of RSA measurements in

this hospital.

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).

Study objective

The goal of this clinical investigation is to assess the early migration of the Symax stem and the precision of the RSA measurements done at this hospital. Also clinical outcome and patient satisfaction will be assessed.

Study design

This is a prospective clinical follow up study with a group of 26 patients who will receive a RSA Symax hip stem. The selection of a control group was not

possible since there are no RSA hip stems of comparable hip prosthesis.

Intervention

The study population will get a cementless RSA Symax hip arthroplasty. To do the symax measurements correctly a number of tantallum markers will be inserted into the femur during surgery. This will lead to a minor lengthening of operating time. A few days after surgery and during the follow up period thereafter a number of RSA X-rays will be made.

Study burden and risks

During this study a number of RSA X-rays will be made. At some follow ups these X-rays will replace the normally made X-rays to minimize the radiation load of the patients. Patients will also be asked to fullfill two questionnaires at regular intervals.
The measurements of early migration will benifit the patient and has to be researched in this catagory of patients.

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

age between 18 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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	26
Type:	Anticipated

Ethics review

Approved WMO Date:	18-01-2008
Application type:	First submission
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	NL16089.068.07