Comparative roentgen stereophotogrammetry wear analysis between the X-3 PE insert and the N2Vac PE insert in the Trident metal backed hemispherical cup with attached markers in primary uncemented total hip arthroplasty with the ABGII femoral stem

Published: 12-10-2006
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The objective is to compare the wear during the years in the two different cups. And if the wear measured on the X-rays is comparable with the daily inconvenience and satisfaction of the patient.

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

Summary

ID

NL-OMON29986

Source
ToetsingOnline

Brief title
RSA wear analysis of the X-3 PE insert

Condition

- Joint disorders

Synonym
arthrosis, total hip arthroplasty

Research involving
Human

Sponsors and support

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

Intervention

Keyword: RSA, THA, wear, X-3 insert

Outcome measures

Primary outcome

Wear (size and direction)

Harris Hip Score

Womac and SF-36 (satisfaction and function)

Secondary outcome

none

Study description

Background summary

The replacement of the hip is done in patients that experience pain and have a reduced function in the joint and it is done to improve function and better return in the community. The last couple of years a lot of research has been done to lengthen the survival of prothesis, in which the patient can postpone the revision surgery. During a ervision surgery a part of the prosthesis will be replaced because of wear or loosening. When the prosthesis is used wear could be seen in the polyethyleen part, when wear is visible patients could experience inconvenience of the prosthesis. A new cup is developed with highly crossed linked polyethyleen that will probably have lesser wear. If this can be determined a revision is not always necessary.

Study objective

The objective is to compare the wear during the years in the two different

cups. And if the wear measured on the X-rays is comparable with the daily inconvenience and satisfaction of the patient.

Study design

During the study the patients included in the study will have the same routine control moments (6 weeks, 1, 2, 3 and 5 years) as patients not included in the study.

Intervention

One group receives an ABGII Stem with a X-3 PE insert and an Trident cup and the other group receives an ABGII stem with a N2VAc PE insert and an Trident cup

Study burden and risks

The patients will have the same risks and benefits as patients not included in the study and receiving an total hip prosthesis. The difference between study patients and patients not included in the study is that study patients have to make an extra roentgen foto (RSA-photo) when they have their control moments to detect the wear. On these photos wear is better visible. This will cause no more or other harm than the standard X-rays.

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

- young patients in the age of 18-65 years
- need uncemented primary THA
- diagnosed with osteoarthritis or avascular necrosis

Exclusion criteria

- other clinical relevant disorders to the hip
- patient received a THA on contralateral side more than 6 months ago but rehabilitation was considered unsatisfactory

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	16-07-2007
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	X-3 PE insert
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL11792.096.06