A comparison of the wear rate of two polyethylene acetabular liners.;A Randomized Controlled Trial

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Primary objectiveTo compare the wear rate 60 months after THA of HXLPE stabilized with vitamin E versus conventional UHMWPE for total joint arthroplasty. Secondary objectives- To compare the wear rate at 3,12, 24 and 60 months after THA between...

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

Summary

ID

NL-OMON34388

Source
ToetsingOnline

Brief title
HipVit

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
coxarthosis, hip arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Clinical Orthopedic Research Center

(onderdeel van maatschap Orthopedie Diakonessenhuis). Dit is een onderzoekscentrum dat financieel gesteund wordt door de maatschap orthopedie> Daarnaast is er een aanvraag gedaan bij het onderzoeksfonds van het Diakonessenhuis (SWODU).

Intervention

Keyword: polyethylene, total hip arthroplasty, wear

Outcome measures

Primary outcome

The primary final study point is the polyethylene wear rates. Measuring is

based on anterior-posterior (AP) radiographs at 3,12,24 and 60 months using a

computer-assisted edge-detection system (ROGAN Delft, VPX ortho)

The software calculates femoral head displacement (mm) as a representation of

wear rate (mm/year)

Secondary outcome

Pain level will be determined using a 10-point Visual Analog Scale (VAS), in

which 0 implies no pain and 10 implies the worst possible pain.

4 questionnaires:

- Harris Hip Score: reflecting both function and pain

- The Short-Form 36 (SF-36): representing eight health domains that are

combined into a physical and a mental component scale.

- The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC):

focusing on joint pain, stiffness and loss of function related to

osteoarthritis of hip.

- Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH):

Functional status and activity level

Complication rates: infection, neurovascular injury, malpositioning of the

prosthesis, asceptic loosening of the prosthesis and dislocation.

Study description

Background summary

Total hip arthroplasty is a widely successful procedure, nevertheless their survivorship has been limited by aseptic loosening and osteolysis secondary to wear of the ultrahigh molecular weight polyethylene (UHMW-PE) in acetubular components.
In response to the problem of UHMW-PE wear, highly cross-linked polyethylene (HXLPE) for application in orthopaedic surgery was developed to reduce wear of UHMW-PE. The wear resistance of HXLPE used in total joint arthroplasty has been shown improve significantly with cross-linking. Cross-linking of PE is achieved through the use of ionizing radiation. Ionizing radiation forms free radicals in polyethylene. These free radicals recombine with each other and form cross-links in the polymer. However, the free radicals generated during irradiation become trapped and affect the long-term oxidative stability of the material, causing embrittlement of the PE component .The most effective method of stabilization is to melt the irradiated PE, which reduces the concentration of the residual free radicals to undetectable levels.The method of irradiation and melting improves the wear resistance and does not compromise the oxidation resistance of PE. However, the post irradiation melting step reduces the mechanical properties and fatigue strength of irradiated PE
A new generation of cross-linked PE has been developed by stabilizing PE by addition of vitamin E, avoiding post irradiation melting. The major physiological role of vitamin E is to react with free radicals and protect against oxidative degradation. This would lead to double advantage of

preventing long-term oxidation and preserving mechanical properties.

Study objective

Primary objective
To compare the wear rate 60 months after THA of HXLPE stabilized with vitamin E versus conventional UHMWPE for total joint arthroplasty.

Secondary objectives
- To compare the wear rate at 3,12, 24 and 60 months after THA between HXLPE stabilized with vitamin E versus conventional UHMWPE.
- To assess the effect of activity level (SQUASH activity scale) on wear rates in HXLPE stabilized with vitamin E versus conventional UHMW polyethylene.
- To assess the clinical performance (HHS score, WOMAC, SF-36, SQUASH) preoperative and 3,12, 24 and 60 months after THA between HXLPE stabilized with vitamin E versus conventional UHMWPE.
- To assess the rate of complications, revisions and mortality between HXLPE stabilized with vitamin E versus conventional UHMW polyethylene.

Study design

Randomized controlled trial of 200 patients subjected to a total hip arthroplasty. The first group involves a HXLPE stabilized with Vitamin E (RM cementless monoblock pressfit Vitamys® cup, Mathys AG Bettlach). The second group involves a conventional UHMW polyethylene (RM cementless monoblock pressfit®, Mathys AG Bettlach). The PE wear will be monitored 3, 12, 24 and 60 months after surgery. The function of the hip will be monitored at regular interval just before surgery and 3, 12, 24 and 60 months after surgery.

Intervention

Total Hip Arthroplasty
Total Hip Arthroplasty will be performed using the RM cementless monoblock pressfit cup (Mathys AG Bettlach) or the RM cementless monoblock pressfitt Vitamys cup (Mathys AG Bettlach). Critical aspects of the surgical procedure will be standardized.

RM Pressfit
RM cementless monoblock pressfit cup is a standard implant.

The implant is made of:
Structure: Elliptical design and a slight polar flattening
Polyethylene: UHMW- PE
Coating material: Pure titanium particles (TiCP)

RM pressfitt Vitamys
RM cementless monoblock pressfit cup stabilized with Vitamin E.
The Vitamys cup is a polyethylene from the same raw material as UHMWPE which has been highly cross linked and additionally endowed with 0.1% of vitamin E, an antioxidant also called tocopherol. The average content of Vitamin E in a Vitamys cup is around 50 mg (max daily amount 400mg)

The implant is made of:
Structure: Elliptical design and a slight polar flattening
Polyethylene: UHMW- PE added with natural anti-oxidant, vitamin E.
Coating material: Pure titanium particles (TiCP)

RM cementless monoblock pressfit Vitamys cup is a CE marked implant and an approved HXLPE for total hip replacements (according to ISO standards 5834-2).

Study burden and risks

Both treatments that patients can be allocated to are standard of care treatments. Participants should not expect any personal benefits from their participation in this study. Their participation may help other people with primary or secondary arthritis of the hip in the future. As with any surgical procedure, potential risks for THA surgery include the following:
- Infection
- Neurovascular injury (injury to the nerves or vessels)
- Death
During the entire study, 6 X-rays will be made as part of Standard Of Care. There are no other known additional risks involved in this study, aside from the inconvenience of completing a set of questionnaires, which will take approximately 15 minutes at each visit. In total, each clinical FU visit will take 25 minutes. Participants will be informed about any new information that might affect their
willingness to continue to participate in this research

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 scheduled for a total hip arthroplasty. Inclusion criterion, patients diagnosed for coxarthrosis, dysplastic coxarthrosis, rheumatoid arthritis, necrosis of the head of the femur or posttraumatic coxarthrosis. Patients between 55 and 75 years old at the time of inclusion. Patient radiographic templated for a 32mm femoral head prosthesis

Exclusion criteria

Exclusion criteria; patients designated for revision surgery, suffer from sepsis, malignant tumours, severe diabetes mellitus (ASA >II), severe cardiovascular diseases (ASA>II)

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):	12-07-2011
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	RM cementless monoblock pressfit cup stabilized with vitamin E (Vitamys cup)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-08-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL32832.100.10
Other	TC = 2229