Wear rate of a Highly Cross-Linked polyethylene stabilized with vitamin E in Total Hip Arthroplasty.;A Randomized Controlled Trial

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2.1 Primary objectiveTo compare the wear rate 24 months after THA of HXLPE stabilized with vitamin E versus conventional UHMWPE for total joint arthroplasty.2.2 Secondary objectives1. To compare the wear rate at 3,12 and 24 months after THA between...

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON34827

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)

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 and 24 months using a computer-assisted edge-detection system (ROGAN Delft, VPX ortho)
The software calculates femoral head displacement (mm) and the angle (°) as a representation of wear.

Secondary outcome

Harris Hip Score, reflecting both function and pain The subjective variables are pain activities of daily living. The objective variables are range of motion and hip positioning which give a total of 100 points. ROM includes flexion, extension, abduction, adduction, external rotation and internal rotation measured using a goniometer

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.

The Short-Form 36 (SF-36), is a validated multi-purpose, short-form health survey with 36 questions, representing eight health domains that are combined

into a physical and a mental component scale.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a 24-item questionnaire completed by the patient and focusing on joint pain, stiffness and loss of function related to osteoarthritis of hip.

Functional status and activity level will be assessed with the Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH).

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

2.1 Primary objective
To compare the wear rate 24 months after THA of HXLPE stabilized with vitamin E versus conventional UHMWPE for total joint arthroplasty.

2.2 Secondary objectives
1. To compare the wear rate at 3,12 and 24 months after THA between HXLPE stabilized with vitamin E versus conventional UHMWPE.
2. To assess the effect of increased head size on wear rates in HXLPE stabilized with vitamin E versus conventional UHMWPE.
3. To assess the effect of activity level (SQUASH activity scale) on wear rates in HXLPE stabilized with vitamin E versus conventional UHMW polyethylene.
4. To assess the clinical performance (HHS score, WOMAC, SF-36, SQUASH) preoperative and 3,12 and 24 months after THA between HXLPE stabilized with vitamin E versus conventional UHMWPE.
5. 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 and 24 months after surgery. The function of the hip will be monitored at regular interval just before surgery and 3, 12, 24 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 ingredients are homogeneously mixed, sintered under pressure, and highly cross-linked by an irradiation dose of 100kGy.

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. All surgeons perform THA as used in the two groups of this trial. 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, 5 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

All 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 20 and 75 years old at the time of inclusion.

Exclusion criteria

Exclusion criteria; patients designated for revision surgery, suffer from sepsis, malignant tumours, severe diabetes mellitus, 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:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	06-05-2010
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

ID: 23978
Source: NTR
Title:

In other registers

Register	ID
Other	Aangemeld bij Nederlands Trialregister. Binnen 4 weken is NCT nummer bekend.
CCMO	NL31682.100.10
OMON	NL-OMON23978