Wear, bone density, functional outcome and survival of vitamin E incorporated polyethylene cups in reversed hybrid total hip arthroplasty: a randomized controlled trial

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

Summary

ID

NL-OMON53149

Source
ToetsingOnline

Brief title
E-Vita

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
degenerative hip joint disease, osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: bedrijf,Zimmer Biomet

Intervention

Keyword: polyethylene, Total hip arthroplasty, vitamin E, wear

Outcome measures

Primary outcome

The primary objective is to compare polyethylene wear (mm/year) at 10 years

between the 2 groups.

Secondary outcome

Secondary parameters are:

1. polyethylene wear (mm/year) at 1 and 3 years postoperatively

2. relative decrease/increase in acetabular BMD at 1 and 2 years postoperatively

3. acetabular and proximal femoral osteolytic changes at 1, 3 and 10 years

postoperatively.

4. patient-reported (Oxford Hip Score) and physician-reported (Harris Hip

Score) functional outcome at 6 weeks and 1, 3, 5, 7 and 10 years

postoperatively.

5. quality of life (SF-36) and physical activity behaviour (SQUASH) at 1, 3, 5,

7 and 10 years postoperatively.

6. survival (number of revisions) determined at 5 and 10 years postoperatively.

Study description

Background summary

Uncemented total hip replacement is a widely used treatment in young patients with osteoarthritis of the hip (age < 70). One of the most important factors determining late implant failure in total hip replacement is aseptic loosening of the cup. There is evidence that hemispheric uncemented cups show a higher tendency in periacetabular osteolysis due to increased polyethylene (PE) wear in contrast to cemented cups. In addition, in vitro testing of PE cups incorporated with vitamin E shows good wear and increased mechanical properties. This is due to the anti-oxidant effect of vitamin E preventing weakening of the polyethylene after crosslinking. Therefore, cementation of a vitamin E stabilized PE cup, combined with an uncemented stem (a reversed hybrid total hip prosthesis) might lead to less PE wear in contrast to the use of a PE cup without vitamin E.

Furthermore, the influence of vitamin E stabilized PE cups on acetabular bone mineral density (BMD) is unknown. Hypothetically, it might lead to changes in acetabular bone mineral density due to different mechanical properties.

Finally, it is hypothesized that less osteolysis will develop in reversed hybrid total hip arhroplasty combined with vitamin E-stabilized PE cups.

Study objective

The primary objective is to compare polyethylene wear at 10 years between a reversed hybrid total hip arthroplasty with vitamin E stabilized polyethylene versus a reversed total hip arthroplasty without the adjunction of vitamin E to polyethylene.

Secondary objectives are to determine whether there are differences between the 2 groups:
1. in polyethylene wear at 1 and 3 years postoperatively
2. in acetabular bone mineral density at 1 and 2 years postoperatively.
3. in acetabular and proximal femoral osteolytic changes at 1, 3 and 10 years postoperatively.
4. in patient-reported and physician-reported functional outcome at 6 weeks and 1, 3, 5, 7 and 10 years postoperatively.
5. in quality of life and physical activity behaviour at 1, 3, 5, 7 and 10 years postoperatively.
6. in survival determined at 5 and 10 years postoperatively.

Study design

Double-blinded randomized controlled trial

150 patients

75 patients reversed hybrid + vitamin E

75 patients reversed hybrid - vitamin E

Intervention

Both investigated groups will receive a total hip arthroplasty (reversed hybrid: cemented cup and uncemented stem) as is performed in usual daily practice. The only difference is the adjunction of vitamin E in group 1 to the polyethylene.

Both groups:
- cemented cup, using Gentamycine cement (Palacos®R+G, Heraeus), applying modern cementing techniques including lavage and pressurization.
- cementless 28 mm femoral component: a proximally plasma sprayed porous coated titanium alloy (Ti6Al4V) stem (Mallory-Head, Biomet).

Group 1:
- cemented vitamin E stabilized polyethylene acetabular component (Exceed ABT Cemented Cup System, E1 Antioxidant Infused Technology, Biomet)

Group 2 (control group):
- cemented polyethylene acetabular component without the adjunction of vitamin E (Exceed ABT Cemented Cup System, ArCom, Biomet).

Study burden and risks

X-rays and/or DEXA-scans will be performed postoperatively as follows: 6 weeks (X-ray and DEXA-scan), 1 (X-ray and DEXA-scan), 2 (only DEXA-scan), 3 and 10 years (only X-rays). Patients will be asked to fill out questionnaires at 6 weeks, 1, 3, 5, 7 and 10 year postoperatively.
No extra visits have to be made, except for the DEXA-scans. These will be performed separately (3 times). The remaining data will be gathered during standard visits to the outpatient clinic which will take only a few minutes extra.

Except for the usual risks of a total hip arthroplasty procedure, an extra (minimal) risk is added due to the DEXA-scans. However, this radiation exposure is neglectable (one DEXA-scan resembles 2 days of natural background radiation)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Primary osteoarthritis of the hip
2. Age < 70 years

Exclusion criteria

1. Secondary osteoarthritis of the hip
2. (Active) arthritis (eg rheumatic disease)
3. Peripheral neuropathy
4. History of CVA
5. Cognitive impairments (eg dementia)

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-12-2011
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Polyethylene with or without adjunction of vitamin E as the acetabular component of a total hip pros
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-11-2011
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	11-07-2016
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	29-11-2022
Application type:	Amendment

Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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: 22433
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL37132.099.11
Other	volgt
OMON	NL-OMON22433