# WEAR, BONE DENSITY, FUNCTIONAL OUTCOME AND SURVIVAL IN VITAMIN E INCORPORATED CUPS IN TOTAL HIP ARTHROPLASTY: A RANDOMIZED CONTROLLED TRIAL.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22433

**Source**
NTR

**Brief title**
E-VITA

**Health condition**

Total Hip Arthroplasty, Vitamin E, polyethylene, wear

### Sponsors and support

**Primary sponsor:** Martini Hospital, Department of Orthopaedic Surgery; University Medical Center Groningen (UMCG), Department of Orthopaedic Surgery
**Source(s) of monetary or material Support:** Martini Hospital, Department of Orthopaedic Surgery; Biomet Nederland, Dordrecht

### Intervention

## Outcome measures

### Primary outcome

Polyethylene wear (mm/y) at 10 years postoperatively.

### Secondary outcome

1. Polyethylene wear at 1, 3, 5 and 7 years postoperatively;

2. Relative decrease/increase in acetabular bone mineral density (BMD) at 1 and 2 years postoperatively;

3. Acetabular and proximal femoral osteolytic changes at 1, 3, 5, 7 and 10 years postoperatively;

4. Patient-reported functional outcome, health related quality of life and physical activity (HOOS) and physician-reported functional outcome (Harris Hip Score) at 6 weeks and 1, 3, 5, 7 and 10 years postoperatively;

5. Physical activity behaviour (SQUASH) at 1, 3, 5 and 10 years postoperatively;

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

# Study description

### Background summary

N/A

### Study objective

Incorporation of vitamin E to a polyethylene acetabular cup gives less wear at 10 years compared to cross-linked polyethylene without vitamin E.

### Study design

See above.

### Intervention

Both investigated groups will receive a reversed hybrid total hip arthroplasty. Gentamycine cement (Palacos®R+G, Heraeus) will be used for cup fixation, applying modern cementing

techniques including lavage and pressurization. In both groups, the same cementless 28 mm femoral component is used: A proximally plasma sprayed porous coated titanium alloy (Ti6Al4V) stem (Mallory-Head, Biomet) with a cobalt-chromium-molybdenum 28 mm femoral head.

One group will receive a cemented vitamin E stabilized polyethylene acetabular component (E1 Muller cup, Exceed ABT Cemented Cup System, Biomet). The other group will receive a cemented polyethylene acetabular component without the adjunction of vitamin E (ArCom Muller cup, Exceed ABT Cemented Cup System, Biomet).

According to the surgeon’s preference, a posterolateral or anterolateral surgical approach in lateral decubitus position is used. Antibiotic prophylaxis with a first-generation cephalosporin will be given preoperatively and during the first twenty-four hours intravenously.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients with non-inflammatory degenerative joint disease of the hip, scheduled for a primary unilateral total hip arthroplasty;

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 impairment (eg dementia).

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2011 |
| Enrollment: | 150 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 29-08-2011 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 53149
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL2903 |
| NTR-old | NTR3049 |
| CCMO | NL37132.099.11 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON53149 |

# Study results

**Summary results**
N/A