# Early stability of the Delta-TT cup with Polyethylene insert compared to the Delta-TT cup with Ceramic insert. A RSA study.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25653

**Source**
Nationaal Trial Register

**Brief title**
Delta-TT cup stability

**Health condition**

Roentgen Stereophotogrammetric Analysis
Osteoarthritis
Primary total hip replacement
Prothesis
Cup
Stability

### Sponsors and support

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## Intervention

## Outcome measures

### Primary outcome

The main study parameter is the early stability of the Delta-TT cup with Polyethylene insert, the Delta-TT cup with Ceramic insert and the H-MAX femoral stem after two years by means of RSA. The RSA migration data of the components will be described in terms of translational and rotational movements.

### Secondary outcome

Secondary study parameter is the stability of the C2 femoral stem and compare the migration results with the migration results of the H-MAX femoral stem as well as relevant migration results of similar stems from the literature. The RSA migration data of the components will be described in terms of translational and rotational movements.

The third study parameter is to predict the long-term survival of the different implants based on the two and five-year migration patterns and correlate the clinical factors, clinical scores and radiographic aspects with the RSA results.

# Study description

### Background summary

Rationale: Roentgen
Stereophotogrammetric Analysis (RSA) is a very accurate measurement technique used to obtain micromotion of the implants relative to inserted tantalum markers in the surrounding bone. Using RSA, long-term predictions of prosthetic loosening can be made based on a two years follow-up. Therefore, it is recommended to analyse all (new) prosthetic components by means of RSA.

Objective: The goal of this study is to study in a randomised trial the stability of the Delta-TT cup with polyethylene insert and the Delta-TT cup with ceramic insert both combined with the H-MAX femoral stem by means of RSA to assess whether the differences in stiffness of the cup will have an influence on incorporation and mechanical stability. It is hypothesized that there will be more micromotion on the short-term (<2 years) in the patients with the ceramic insert because of the higher stiffness, however, all components will be considered stable on the short and long-term. Secondary goal is to compare the stability of the C2 femoral stem, to the H-MAX femoral stem as well as to compare it to relevant migration results of similar stems from the literature. These RSA results will contribute to knowledge about the early stability and long-term prosthetic loosening of these cementless stems.

Study design: A Prospective Randomized Single Centre RSA Study (Group A and B) combined with a non-randomised treatment group (Group C)

Study duration: 18 months enrolment period + up to 5 year follow-up = 6.5 years total duration.

Study population: Primary total hip replacement
Number of patients: 65 patients

Study Devices: Delta-TT cup in combination with a polyethylene insert or a ceramic insert; H-MAX femoral stem; C2 femoral stem.

Intervention: Group A: 25 patients will be randomised to receive the H-MAX femoral stem and the Delta-TT cup with polyethylene insert. Group B: 25 patients will be randomised to receive the H-MAX femoral stem and the Delta-TT cup with ceramic insert. Group C: 15 patients will receive the C2 femoral stem and the Delta-TT cup with ceramic insert (non-randomised).
Main study parameters/endpoints: The main study parameter is the early stability of the Delta-TT cup with Polyethylene insert, the Delta-TT cup with Ceramic insert and the H-MAX femoral stem by means of RSA. The RSA data of the components will be described in terms of translational and rotational movements.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In addition to the benefits from the primary hip arthroplasty procedure e.g. reduced pain, improved range of motion, there is no guarantee that patients will personally benefit from inclusion in this study. Patients may undergo more thorough screening and follow-up than non-study patients and may benefit from this increased surveillance. The additional annual radiation dose is negligible if the natural annual exposure of 2 mSv is considered and will do the patient no harm.

## Study objective

It is hypothesized that there will be more micromotion on the short-term (<2 years) in the patients with a Delta-TT cup and ceramic insert as compared to a polyethylene insert, because of the higher stiffness, however, all components will be considered stable on the short and long-term.

**Study design**

Pre-operative, discharge, 6 weeks, 3, 6, 12 months, 2 and 5 years.

**Intervention**

Randomized trial:

• Group A: 25 patients will receive the H-MAX femoral stem and the Delta-TT cup with polyethylene insert.

• Group B: 25 patients will receive the H-MAX femoral stem and the Delta-TT cup with ceramic insert.

Non-randomised group:

• Group C: 15 patients will receive the C2 femoral stem and the Delta-TT cup with ceramic insert. Group C will be included when inclusion of group A and B is completed.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Patients scheduled to undergo primary total hip replacement.
Patient is able to understand the meaning of the study and is willing to sign the EC approved, study-specific Informed Patient Consent Form.
Ability and willingness to follow instructions and to return for follow-up evaluations.
The subject is a male or non-pregnant female between 18 and 75 years of age.

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40.

The subject will be operated bilaterally.
Patients having a deformity or disease located in other joints than the hip that needs surgery and is limiting their ability to walk.

The subject has an active or suspected latent infection in or about the hip joint.
Patient who is expected to need lower limb joint replacement for another joint within one year.
The subject has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.

The subject has a systemic or metabolic disorder leading to progressive bone deterioration.

The subject’s bone stock is compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.

Female patients planning a pregnancy during the course of the study.

The patient is unable or unwilling to sign the Informed Consent specific to this study.

Subject deemed unsuitable for participation in the study based on the investigator’s judgement.

# Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2013 |
| Enrollment: | 65 |
| Type: | Anticipated |

## Ethics review

Not applicable

| | |
|---|---|
| Application type: | Not applicable |

## Study registrations

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

ID: 41576
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL3803 |
| NTR-old | NTR3990 |

| Register | ID |
| --- | --- |
| CCMO | NL44230.100.13 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON41576 |

# Study results