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

Gepubliceerd: 14-05-2013 Laatst bijgewerkt: 15-05-2024

It is hypothesized that there will be more micromotion on the short-term (

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25653

Bron
Nationaal Trial Register

Verkorte titel
Delta-TT cup stability

Aandoening

Roentgen Stereophotogrammetric Analysis
Osteoarthritis
Primary total hip replacement
Prothesis
Cup
Stability

Ondersteuning

Primaire sponsor: Link Nederland
Havenstraat 30
3115 HD Schiedam
The Netherlands
Phone: +31(0) 10 246 26 95

Fax: +31(0) 10 246 26 96
info@linknederland.nl
Overige ondersteuning: Link Nederland
Havenstraat 30
3115 HD Schiedam
The Netherlands
Phone: +31(0) 10 246 26 95
Fax: +31(0) 10 246 26 96
info@linknederland.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Onze Lieve Vrouwe Gasthuis Amsterdam
Department of Orthopaedic Surgery

Postbus 95500

R.W. Poolman
Oosterpark 9

Amsterdam 1090 HM
The Netherlands
+31 (0)20 5999111

Wetenschappelijk

Onze Lieve Vrouwe Gasthuis Amsterdam
Department of Orthopaedic Surgery

Postbus 95500

R.W. Poolman
Oosterpark 9

Amsterdam 1090 HM
The Netherlands
+31 (0)20 5999111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	65
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41576
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3803
NTR-old	NTR3990

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

Resultaten