Fixatie en migratie van het G7 BiSpherical acetabulair systeem gecombineerd met de GTS steel voor totale heupvervanging- een RSA studie.

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The G7 BiSpherical acetabular system and the GTS femoral stem will have acceptable migration patterns at the two-year follow-up mark (G7 BiSpherical acetabular system) and at six months (GTS femoral stem)

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Skeletspierstelsel- en bindweefselaandoeningen NEG
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24421

Bron
NTR

Verkorte titel
G7-GTS RSA

Aandoening

- Skeletspierstelsel- en bindweefselaandoeningen NEG

Aandoening

Hip osteoarthritis, Prosthesis, Implant technical complications, Arthroplasty, Radio Stereometric Analysis, Unicondylar

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Zimmer Biomet
Overige ondersteuning: Zimmer Biomet

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fixation and migration patterns of the G7 acetabular system and GTS femoral stem in vivo, using model-based RSA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cementless total hip arthroplasty (THA) has very good clinical results. As a result of the success, the ageing population and because the procedure is performed in increasingly younger and more active patients, the number of THA procedures has increased the last decades. After failure of a primary THA, a more challenging and costly hip revision surgery is needed, mainly due to management of the bone stock loss. Therefore, the new shorter GTS stem was developed to prevent the loss of bone stock.

Nowadays the risk of poor performing survival over time should be limited. The only clinical test that can provide data to predict long survival is stability testing with RSA. As a result, the risk of implanting potentially inferior prostheses in patients will be reduced, resulting in less suffering for patients and a reduction in healthcare expenses.

This study identifies the radiographic outcomes, implant survival, fixation and migration patterns of the G7 BiSpherical acetabular system combined with the GTS stem, up to five years after implantation.

Objective: Identifying the fixation and migration patterns of the G7 BiSpherical acetabular system combined with the GTS stem (Zimmer Biomet) prosthesis in vivo, using model based roentgen radiostereophotogrammetric (mRSA) analysis over a period of 5 years.

Study design: A prospective clinical trial in which 25 cases will be enrolled over one hospital.

Patients will be evaluated preoperatively and postoperatively at discharge (from operation date to date of discharge), at 6 weeks, 6 months, 1 year, 2 years and 5 years.

Study population: The study population consists of active male or non-pregnant female 18-75 years of age. The subjects have no clinical relevant disorders of the hip and they will undergo a hip arthroplasty with the G7 BiSpherical acetabular system combined with the GTS stem, after diagnosis of osteoarthritis.

Intervention (if applicable): Placement of the G7 BiSpherical acetabular system combined with the GTS stem.

Main study parameters/endpoints: Outcome will be clinically measured using the HOOS-PS, EQ5-D and OHS whilst radiographic outcomes will be evaluated through standard radiographic parameters. RSA will be used to measure migration of the prosthesis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects participating in the study have the same risks and benefits when not participating in the study. All components used in the study have CE mark and are already in use. Besides standard radiological follow-up, RSA x-rays will be made to measure the fixation of the prosthesis.

Doel van het onderzoek

The G7 BiSpherical acetabular system and the GTS femoral stem will have acceptable migration patterns at the two-year follow-up mark (G7 BiSpherical acetabular system) and at six months (GTS femoral stem)

Onderzoeksopzet

• Pre-operative

• 6 weeks

• 6 months

• 1 year

• 2 years

• 5 years

Onderzoeksproduct en/of interventie

Placement of the G7 BiSpherical acetabular system and the Global Tissue Sparing (GTS) femoral stem, with insertion of tantalum beads for radiostereophotogrammetric analysis(RSA)

Contactpersonen

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The G7 BiSpherical cup and GTS stem are intended for patients with the following indications for THA:

• Noninflammatory degenerative joint disease (e.g. OA, avascular necrosis) (although there are more indications for the G7BiSpherical cup and GTS stem, subjects in this study must have a primary diagnosis of noninflammatory degenerative joint disease. Additional indications may be present)

• Rheumatoid arthritis

• Correction of functional deformity

• Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques (Although this is an indication for the G7 BiSpherical cup as well as the GTS stem, only patients with primary, elective THA are included in this study. See 'Exclusion criteria')

• Revision procedures where other treatment or devices have failed (Although this is an indication for the G7 BiSpherical cup, patients with previous ipsilateral THA will not be included in this study. See 'Exclusion criteria')

Subjects must additionally meet the following criteria to participate in this study:

• Age >18 years and < 75 years

• Patient is willing to participate

• Patient is able to speak and write Dutch

• Patient qualifies for THA with the G7 BiSpherical cup and GTS stem based on physical exam and medical history

• Patient is able and willing to provide written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will be excluded when they meet one or more of the following contra-indications for the G7 BiSpherical cup and/or GTS stem:

• Infection, sepsis, and osteomyelitis

• Uncooperative patient or patient with neurologic disorders who are incapable of following

directions

• Insufficient bone stock to provide adequate support and/or fixation to the prosthesis

• Metabolic disorders which may impair bone formation

• Osteomalacia

• Distant foci of infections which may spread to the implant site

• Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram

• Vascular insufficiency, muscular atrophy, neuromuscular disease

Additionally, subjects will be excluded when they meet the following exlusion criteria:

• Patients with emergency or semi-emergency THA (e.g. for treatment of femoral neck fractures)

• Patient has a known or suspected sensitivity or allergy to one or more of the implant materials

• Revision THA surgery of the ipsilateral side

• Contralateral THA <6 months before current surgery

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Anders

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-05-2018
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	23-05-2017
Soort:	Eerste indiening
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55980
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6294
NTR-old	NTR6468

Register	ID
Ander register	: 17-060 METC Zuidwest Holland
CCMO	NL61271.098.17
OMON	NL-OMON55980

Resultaten