Fixation and migration of the G7 BiSpherical acetabular system combined with the GTS stem for total hip arthroplasty - an RSA study

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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 10 years.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON55980

Source
ToetsingOnline

Brief title
G7-GTS RSA study

Condition

- Bone and joint therapeutic procedures

Synonym
hip prosthesis, Hip wear/osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum

Source(s) of monetary or material Support: Zimmer Biomet, Warsaw, IN,Zimmer Biomet;Warsaw;IN

Intervention

Keyword: G7 BiSpherical cup, GTS stem, Hip, RSA

Outcome measures

Primary outcome

Outcome will be clinically measured using the HOOS-PS, EQ5-D, OHS and NRS

whilst radiographic outcomes will be evaluated through standard radiographic

parameters. RSA will be used to measure migration of the prosthesis.

Secondary outcome

N/A

Study description

Background summary

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 ten years after implantation.

Study 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 10 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, 5 years and 10 years.

Intervention

Placement of the G7 BiSpherical acetabular system combined with the GTS stem.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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 G7 BiSpherical 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 *4.3 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 *4.3 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

Exclusion criteria

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

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	G7 BiSpherical acetabular system combined with GTS stem
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 24421
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61271.098.17

Register	ID
OMON	NL-OMON24421