A prospective study to evaluate long-term clinical outcomes of the GTS cementless femoral stem

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The objectives of this prospective clinical study are:1. Obtain multi-center, long-term (10-year) clinical data on the new GTS® femoral stem inits standard and lateralized versions2. Collect quality of life data

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55672

Source
ToetsingOnline

Brief title
H36 GTS international

Condition

- Joint disorders

Synonym
Joint wear, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet
Source(s) of monetary or material Support: Biomet GSCC bv

Intervention

Keyword: GTS, Long Term Follow up, Total Hip Prosthesis

Outcome measures

Primary outcome

Mean Harris Hip Score (HHS) at 2 years postoperative

Secondary outcome

-Radiographic evaluation: stability, incidence of radiolucencies around the

prosthesis and

bone remodeling

- Patient satisfaction: EQ5D quality of life

- Adverse Events/Complications (including revisions/removals).

- Survivorship

Study description

Background summary

The Global Tissue Sparing (GTS) stem designed by Biomet in collaboration with Dr Grappiolo,
is a new cementless stem, based on the Spotorno CLS stem design.
Dr Grappiolo carried out a study on morphology and as a result of anatomic analysis concluded
that it was vital for a stem to fulfill varus and valgus needs from a standard stem. As a result of
this study, he initiated the CLS change to 125°. This provided a more flexible system with the
practical applications for covering all morph types.

Study objective

The objectives of this prospective clinical study are:
1. Obtain multi-center, long-term (10-year) clinical data on the new GTS® femoral stem in

its standard and lateralized versions
2. Collect quality of life data

Study design

An international multi centre, prospective, non controlled study, involving 250 patients distributed between GTS standard and lateralized groups.

Study burden and risks

None

Contacts

Public
Zimmer Biomet

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Male and non-pregnant females : >= 18 years and <= 70 years
2. Patients requiring primary THR, suitable for the use of the GTS stem.
3. The patient is diagnosed with osteoarthritis (OA) or avascular necrosis.
4. The individual is physically and mentally willing and able to comply with postoperative functional evaluation and able to participate in an appropriate rehabilitation schedule.
5. ASA classification score I-III.
6. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.
7. Surgical technique is planned to be Anterior Supine Intramuscular (ASI), or patient has already received a GTS hip on the contralateral side.

Exclusion criteria

1. Patients who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome is considered unsatisfactory or not good.
(Patients with contra-lateral THA >6 months ago with good outcome (Harris Hip Score >85) can be included in the study).
2. Patients who had a THA on contralateral side less than 6 months ago.
3. Patients with a major surgical procedure during the 12 weeks before the study-related
operation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2014

Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	Total Hip Prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-07-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-08-2021
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

No registrations found.

In other registers

Register	ID
Other	NCT02851992
CCMO	NL48747.098.14