Prospective Observational Multicenter Evaluation of the Use of the G7 BiSpherical Shell

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This study is a PMCF study to fulfill the post-market surveillance obligations according to Medical Device Directive and MEDDEV 2.12-2. The data collected from this study will serve the purpose of confirming safety and performance of the G7…

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

Summary

ID

NL-OMON46708

Source
ToetsingOnline

Brief title
G7 PMCS study

Condition

- Bone and joint therapeutic procedures

Synonym
hip prothesis, Hip wear/osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: G7 BiSpherical Shell, Hip

Outcome measures

Primary outcome

Implant survivorship: assessed with the Kaplan-Meier method according to the implant revisions.

Secondary outcome

Clinical efficacy: Pain and functional performance will be measured using the Harris Hip Score.

In addition, performance will be evaluated based on the Oxford Hip Score and evaluation of X-rays. The assessment of safety will be evaluated by monitoring the frequency and incidence of adverse device effects in investigational subjects.

Study description

Background summary

The Zimmer Biomet G7 BiSpherical Acetabular Shell belongs to the G7 multi-bearing platform. It was developed to provide an additional surgical option for patients in need of a total hip replacement. The aim of the G7 BiSpherical Acetabular Shell is to increase hip function while reducing pain. This study is a PMCF study to fulfill the post-market surveillance obligations according to Medical Device Directive and MEDDEV 2.12-2.

Study objective

This study is a PMCF study to fulfill the post-market surveillance obligations according to Medical Device Directive and MEDDEV 2.12-2. The data collected from this study will serve the purpose of confirming safety and performance of the G7 BiSpherical Acetabular Shell.

Study design

A multicenter, prospective, non-randomized, non-controlled post market surveillance study involving orthopedic surgeons skilled in hip arthroplasty procedures.

Intervention

Implantation of the G7 bispherical acetabular shell

Study burden and risks

There are no anticipated risks specific to study participation other than the potential loss of confidentiality. There are no experimental procedures in this study, and participation in this study is not anticipated to affect the medical treatment of enrolled patients.
When used in accordance with product labeling, the risks associated with the use of G7 BiSpherical Acetabular Shell are similar to those of standard acetabular cups used for the same clinical indication or purpose.

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

- Patient capable of understanding the surgeon*s explanations and following his instructions, able and willing to participate in the follow-up program and who gave consent to take part in the study.
- Patients aged of 18 years or more whose skeleton reached bone maturity.
- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis.
- 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.
- Revision procedures where other treatment or devices have failed.;Inclusion criteria specific for patients receiving the G7 BiSpherical Shell with the Freedom Constrained Liner:
- The Biomet G7 Freedom Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

Exclusion criteria

- Infection, sepsis, osteomyelitis.
- Uncooperative patient or patient with neurologic disorders who is incapable of following directions.
- Osteoporosis.
- 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.
- Patient unwilling or unable to give consent, or to comply with the follow-up program
- Patient known to be pregnant or breastfeeding.
- Patient presenting any condition that would, in the judgment of the Investigator, place the patient at undue risk or interfere with the study.

- Patient institutionalized or known drug abuser or alcoholic or anyone who cannot understand what is required of them.
- Patient belonging to a vulnerable population: individual whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate. ;Exclusion criteria specific for patients receiving the G7 BiSpherical Shell with the G7
Freedom Constrained Liner:
- Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2019
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	G7 BiSpherical Acetabular Shell
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-10-2018
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-11-2020
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
ClinicalTrials.gov	NCT03266874
CCMO	NL64657.098.18