A Multicentre Observational Study to Evaluate Clinical Outcomes of the G7 Acetabular System

Published: 30-06-2014
Last updated: 23-04-2024

This study intends to evaluate early clinical outcomes and survivorship of the G7 Acetabular System. Ease of instrument use will also be documented.The primary purpose of this study is to evaluate the clinical and radiographic performance of the G7…

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

Summary

ID

NL-OMON50332

Source
ToetsingOnline

Brief title
G7 Early evaluators

Condition

- Bone and joint therapeutic procedures

Synonym
Hip Arthrosis, Hip Wear

Research involving
Human

Sponsors and support

Primary sponsor: Biomet GSCC B.V.
Source(s) of monetary or material Support: Biomet

Intervention

Keyword: Acetabular system, Clinical Outcomes, Hip arthroplasty, Observational

Outcome measures

Primary outcome

Harris Hip Score (HHS) at 2 year postoperative

Secondary outcome

Oxford Hip Score at 1,2,5 year postop

Radiographic Evaluation: radiographic outcome, stability, incidence of

radiolucencies around the prosthesis and bone remodeling

Adverse Events/Complications (including revisions/removals of the study hip).

Survivorship

Study description

Background summary

The always pressing need to provide more surgical options for the treatment of patients needing total hip arthroplasty, while concurrently simplifying the surgical process with well-designed modular components and corresponding instruments, has led to the development of the Biomet G7* Acetabular Cup System. The intended application is for the system to be used in conjunction with the femoral components of a total hip arthroplasty system to reduce hip pain and increase hip function.

Study objective

This study intends to evaluate early clinical outcomes and survivorship of the G7 Acetabular System. Ease of instrument use will also be documented.
The primary purpose of this study is to evaluate the clinical and radiographic performance of the G7 Acetabular Cup System in both primary and revision procedures, report safety and survivorship, and document instrument ease of use.

Study design

This is a global, multicenter, interventional study using three study subgroups, with each of the subgroups including a different articulation of the G7 cup. Patients who already have received the G7 cup, as well as patients who will receive the G7 cup, will be asked to participate.

Subgroup 1
G7 cup with Metal on Polyethylene articulation (MOP)
105 cases

Subgroup 2
G7 cup with Ceramic on Polyethylene articulation (COP)
105 cases

Subgroup 3
G7 cup with Ceramic on Ceramic articulation (COC)
105 cases

Intervention

The use of a G7 cup in total hip replacement.

Study burden and risks

No additional risk or burden for the patient. This study is observational.

Contacts

Public
Biomet GSCC B.V.

Toermalijnring 600
Dordrecht 3316 LC
NL
Scientific
Biomet GSCC B.V.

Toermalijnring 600
Dordrecht 3316 LC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Selection of subjects for this evaluation should be in accordance with the indications of the G7 cup specifically:
Subjects with one of the following indication:
- 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.
Additional inclusion criteria include:
- Male or female.
- 18 years of age or older
- Subjects willing to return for follow-up evaluations.

Exclusion criteria

Exclusion criteria should be in accordance with Contraindications for the G7 cup.
Absolute contraindications include: infection, sepsis and osteomyelitis,
Additional contraindications include:
- Subjects unable to cooperate with and complete the study
- Dementia and inability to understand and follow instructions
- Neurological conditions affecting movement
- Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2014
Enrollment:	21
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	30-06-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	21-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-10-2020
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
CCMO	NL46033.098.13