Global, Multicenter, and Prospective Post-Market Clinical Follow-Up Study of the G7® Acetabular System with Vivacit-E® and Longevity® Highly Crosslinked Polyethylene (HXLPE) Liners & Instrumentation

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

Summary

ID

NL-OMON51238

Source
ToetsingOnline

Brief title
G7 acetabular system with Highly Crosslinked Polyethylene (HXLPE) inlay

Condition

- Joint disorders

Synonym
hip arthritis, hip wear

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Acetabular System, Highly Crosslinked Polyethylene, Liner, Total hip arthroplasty

Outcome measures

Primary outcome

The primary endpoint is defined by the survival of the implant system at 10 years which is based on removal or intended removal of the study device and will be determined using Kaplan Meier method. The safety of the system will be assessed by monitoring the frequency and incidence of adverse events. Relation of the events to implant, instrumentation and/or procedure should be specified.

Secondary outcome

The secondary endpoint is defined by the functional performance and clinical benefits of the study device and is assessed by:

- Pain and functional performance will be measured by the Modified Harris Hip Score, and Physical Exam (up to 5 years), and the Oxford Hip Score (up to 10 years);

- Subject quality-of-life will be measured by the EQ-5D-5L (up to 10 years);

- Radiographs will be evaluated (up to 5 years) for radiolucency, osteolysis, atrophy, hypertrophy, component migration, device fracture, heterotopic ossification, etc.

Study description

Background summary

Degenerative diseases or trauma of the hip can cause pain and disability. When conservative treatments like steroids and/or pain-medication have failed, a hip replacement can be performed as an alternative treatment. This is a surgical procedure, during which the affected joint is replaced by an artificial hip implant (prosthesis). There are many different implants available, one is called the G7 Acetabular System from Zimmer Biomet. The implant is available in different sizes, which allows the investigator to find the right size for your anatomy. If you decide to take part in the study, you will help the investigator, as well as Zimmer Biomet, to provide the scientific basis for a continuous improvement in the treatment of patients with degenerative diseases or trauma of the hip.

Study objective

The main objectives of this study are to confirm the long-term safety, performance, and clinical benefits of the G7 Acetabular Shells when used with the Vivacit-E and Longevity HXLPE liners and instrumentation in primary and revision total hip arthroplasty:
The primary endpoint is defined by the survival of the implant system at 10 years, which is based on removal or intended removal of the study device and will be determined using Kaplan Meier method. The safety of the system will be assessed by monitoring the frequency and incidence of adverse events. Relation of the events to implant, instrumentation and/or procedure should be specified. The secondary endpoints are the assessment of performance and clinical benefits by recording patient-reported clinical outcomes measures (PROMs) as well as radiographic outcomes (if available).

Study design

Global, Multicenter, Prospective, Non-randomized, Consecutive series of patients, Dual cohort study

Study burden and risks

In this study, patients do not experience any additional burden and / or risk. The only risk, is the same risks that patients receive also with regular care. Risks such as the surgical procedure, postoperative infections and loosening of the prosthesis can occur in both study contexts and regular care. Patients return at the same check-up times with questionnaires and X-rays, both in the study and in regular care.

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

- Patient must be a legal adult who has reached full skeletal maturity;
- Patient must be treated for one of the following indications;
o Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
o Rheumatoid arthritis;
o Correction of functional deformity;
o Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques;
o Revision procedures where other treatment or devices have failed
- Patient must be able and willing to complete the protocol required follow-up visits;
- Patient must be able and willing to sign the IRB/EC approved informed

consent.

Exclusion criteria

- Patient presents with osteoporosis, which in the opinion of the Principal Investigator, may limit the subject*s ability to support total hip arthroplasty using the study device;
- Patient has a metabolic disorder that may impair bone formation;
- Patient has osteomalacia;
- Patient has distant foci of infections which may spread to the implant site or patient with infection, sepsis or osteomyelitis;
- Patient has rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram;
- Patient has a vascular insufficiency, muscular atrophy, or neuromuscular disease;
- Patient is a current alcohol or drug abuser;
- Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions;
- Patient is pregnant.

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):	09-05-2022
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	G7® Acetabular System with Vivacit-E® and Longevity®

	Highly Crosslinked Polyethylene
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-03-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NCT03456622
CCMO	NL76141.096.21