Comparison of Zimmer Maxera Acetabular System to the Allofit Cup with Roentgen Stereophotogrammetric Analysis (RSA) in Total Hip Arhtroplasty

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To perform a comparative assessment between the clinical and radiographic outcomes (as measured with RSA) of the Maxera Ceramic cup versus the standard uncemented polyethylene Allofit Cup all combined with the ML Taper stem in patients undergoing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON53013

Source
ToetsingOnline

Brief title
Maxera RSA

Condition

- Joint disorders

Synonym
Hip osteoarthritis, hip wear

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum

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

Intervention

Keyword: RSA, total hip arthroplasty, Zimmer Maxera cup

Outcome measures

Primary outcome

Outcome will be clinically measured using the Harris Hip Score (HHS), Oxford Hip score (OHS) and EQ5-D, whilst radiographic outcomes will be evaluated through standard radiographic parameters which include qualitative femoral and acetabular findings as well as position of the stem and cup. RSA will be used to measure prostheses migration.

Secondary outcome

not applicable

Study description

Background summary

The Maxera Cup provides a large-head, ceramic-on-ceramic option for the younger and more active patient. The cup is an established hemispherical design. It is a cup system that offers high range of motion and a low-wear bearing to better enable the restoration of a patient*s active lifestyle. The wear rates for Biolox delta material have been confirmed in vitro by hip simulator tests. By mixing Zirconia and other oxide additives into the Alumina matrix, a composite is created that results in a significant reduction of the ceramic femoral head fracture rate. Nowadays the risk of poor performing survival over time should be limited to the max. 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.
It is hypothesized that the clinical results, radiographic outcomes, implant survival, overall pain and functional performances of the Maxera Cup are equal

to the Allofit Cup, up to five years of follow-up.

Study objective

To perform a comparative assessment between the clinical and radiographic outcomes (as measured with RSA) of the Maxera Ceramic cup versus the standard uncemented polyethylene Allofit Cup all combined with the ML Taper stem in patients undergoing primary uncemented THA over a period of 5 years (primary objective is stability over 2 years). All complications will be documented.

Study design

A prospective randomised clinical trial in which 50 cases (25 vs. 25) will be enrolled over one hospital. The primary components to be implanted are an uncemented ML Taper stem combined with the uncemented Maxera or Allofit cup cup. All patients will have a Ceramic head. Patients will be evaluated preoperatively and postoperatively at discharge (from operation date to date of discharge), at 6 weeks, 3 months, 6 months,1 year, 2 years and 5 years.

Intervention

Placement of an uncemented Maxera® or Allofit® cup in combination with an uncemented ML Taper 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 prostheses.

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

1. Male and non-pregnant females : <= 75 years
2. Patients with a Quetelet index (QI=weight in (kilogram)/ square length (meters)) < 35.
3. Patients requiring primary THR, suitable for the use of the Maxera Cup and Allofit Cup.
4. The patient is diagnosed with osteoarthritis (OA) or avascular necrosis.
5. The individual is physically and mentally willing and able to comply with postoperative functional evaluation and able to participate in an appropriate rehabilitation schedule.
6. ASA classification score I-III.
7. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.

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.
4. Dutch language not mastered
5. The patient is unwilling to cooperate with the study
6. The patient is pregnant or desired to be pregnant after surgery or is using

inadequate birth control
7. Recent Myocardial infarct or CVA (<3 months).
8. Mentally disabled patients.
9. Patients with a Quetelet index (QI=weight in (kilogram)/ square length (meters)) > 35.
10. Any active infection
11. Current malignancy
12. Uncontrolled hypertension
13. Known history of alcohol or drugs abuse.
14. ASA IV-V

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	07-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	13-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	26-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	05-08-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	21-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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: 26837
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL47440.098.14
OMON	NL-OMON26837

Study results

Date completed:	01-02-2024
Actual enrolment:	54