Early stability of the Delta-TT cup with Polyethylene insert compared to the Delta-TT cup with Ceramic insert. A RSA study.

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

Summary

ID

NL-OMON41576

Source
ToetsingOnline

Brief title
Delta-TT cup stability

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Primary total hip replacement; wear of the hip joint

Research involving
Human

Sponsors and support

Primary sponsor: Limacorporate S.p.A.
Source(s) of monetary or material Support: bedrijven

Intervention

Keyword: Early stability, Primary total hip replacement, RSA

Outcome measures

Primary outcome

The main study parameter is the early stability of the Delta-TT cup with Polyethylene insert, the Delta-TT cup with Ceramic insert and the H-MAX femoral stem after two years by means of RSA. The RSA data of the components will be described in terms of subsidence, linear, and rotational movements.

Secondary outcome

Secondary objective is to study the stability of the C2 femoral stem and compare the migration results with the migration results of the H-MAX femoral stem as well as relevant migration results of similar stems from the literature.

The third objective is to predict the long-term survival of the different implants based on the two and five-year migration patterns and correlate the clinical factors, clinical scores and radiographic aspects with the RSA results.

Study description

Background summary

The acetabulum cup is the weak link in a total hip arthroplasty, with a higher

revision number compared to the femoral stem. Rationale is that the insert influences the modus of elasticity of the cup, which might influence the osseointegration and thus the stability of the device. A titanium shell with a ceramic inlay is stiffer than the same shell with a polyethylene liner. However, the trabeculair titanium outer layer with its tremendous bone ingrowth capacity can even well compensate for this potential negative aspect

Study objective

Primary objective is to assess the early stability of the Delta-TT cup and H-MAX femoral stem. Additionally, the stability of the Delta-TT cup with Polyethylene insert is compared to the Delta-TT cup with Ceramic insert by means of RSA. Secondary objective is to study the stability of the C2 femoral stem and compare the migration results with the migration results of the H-MAX femoral stem as well as relevant migration results of similar stems from the literature. The third objective is to predict the long-term survival of the different implants based on the two and five-year migration patterns and correlate the clinical factors, clinical scores and radiographic aspects with the RSA results.

Study design

A Prospective Randomized Single Centre RSA Study

Intervention

Group A: 25 patients will receive the H-MAX femoral stem and the Delta-TT cup with polyethylene insert.
Group B: 25 patients will receive the H-MAX femoral stem and the Delta-TT cup with ceramic insert.
Group C: 15 patients will receive the C2 femoral stem and the Delta-TT cup with ceramic insert (Cohort).

Study burden and risks

In addition to the benefits from the primary hip arthroplasty procedure e.g. reduced pain, improved range of motion, there is no guarantee that patients will personally benefit from inclusion in this study. Patients may undergo more thorough screening and follow-up than non-study patients and may benefit from this increased surveillance. The effective radiation dose per RSA-radiograph is 3 *Sv. The additional annual radiation dose is negligible if the natural annual exposure of 2 mSv is considered and will do the patient no harm.

Contacts

Public
Limacorporate S.p.A.

Via Nazionale 52
Villanova di San Daniele 33038
IT
Scientific
Limacorporate S.p.A.

Via Nazionale 52
Villanova di San Daniele 33038
IT

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

A. Patients scheduled to undergo primary total hip replacement.
B. Patient is able to understand the meaning of the study and is willing to sign the METC approved, study-specific Informed Patient Consent Form.
C. Ability and willingness to follow instructions and to return for follow-up evaluations.
D. The subject is a male or non-pregnant female between 18 and 75 years of age.

Exclusion criteria

A. The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40.
B. The subject will be operated bilaterally.
C. Patients having a deformity or disease located in other joints than the hip that needs

surgery and is limiting their ability to walk.
D. The subject has an active or suspected latent infection in or about the hip joint.
E. Patient who is expected to need lower limb joint replacement for another joint within one year.
F. The subject has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.
G. The subject has a systemic or metabolic disorder leading to progressive bone deterioration.
H. The subject*s bone stock is compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.
I. Female patients planning a pregnancy during the course of the study.
J. The patient is unable or unwilling to sign the Informed Consent specific to this study.
K. Subject deemed unsuitable for participation in the study based on the investigator*s judgement.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2014
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2014

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-06-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 25653
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ISRCTN	ISRCTNvolgt
CCMO	NL44230.100.13
OMON	NL-OMON25653