Comparative roentgen stereophotogrammetry analysis (RSA) between the conventional Mallory- Head stem in primary uncemented total hip replacement compared to two shorter variations

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Objective: To perform a comparative assessment between the clinical, bone remodelling, and radiographic outcomes (as measured with RSA) of the conventional Mallory-Head stem compared two shorter versions of Mallory-Head stems in patients undergoing...

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

Summary

ID

NL-OMON39428

Source
ToetsingOnline

Brief title
RSA short Mallory-head total hip prosthesis

Condition

- Bone and joint therapeutic procedures

Synonym
disabled hip, osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W,BioMet,de RSA box wordt gesponseerd

Intervention

Keyword: Orthopaedic, RSA, uncemented total hip, young patient

Outcome measures

Primary outcome

Main study parameters/endpoints: Outcome will be clinically measured using the

Harris Hip Score (HHS), HOOS / WOMAC questionnaire, SF-12, (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 stem migration.

Secondary outcome

n.a.

Study description

Background summary

Rationale: The stem length must be minimised with assurance that bone stock is adequate for stability. The use of a stem is important to resist varus/valgus stress, but it should be as short as possible and with a flexibility as close to that of the femur as possible to decrease the compressive stresses to the lateral femoral cortex.

Study objective

Objective: To perform a comparative assessment between the clinical, bone remodelling, and radiographic outcomes (as measured with RSA) of the

conventional Mallory-Head stem compared two shorter versions of Mallory-Head stems in patients undergoing primary uncemented THA over a period of 5 years. Bone remodelling and all complications will be documented.

Study design

Study design: A prospective randomised clinical trial in which 60 cases will be enrolled. The primary components to be implanted are an uncemented Mallory head uncemented cup in combination with the short stem Mallory-Head®, the middle length or the conventional Mallory-Head stem®. All patients will receive a 28 mm Cobalt chrome head. Patients will be evaluated preoperatively and postoperatively at discharge (from operation date to date of discharge), at 3 months, 1 year, 2 years, 3 years and 5 years.

Intervention

Intervention: Placement of an uncemented primary Mallory-Head® cup in combination with either the Mallory-Head short stems or the conventional Mallory-Head stem for primary uncemented THA.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects participating in the study have the same risks and benefits when not participating in the study. The new components used in the study are based on designs already in use. The Mallory-Head is clinically successfully used with an unchanged design since 1987. Follow-up times are standard protocol evaluations of prothesis. Besides standard radiologic follow-up, RSA x-rays will be made to measure the fixation of the stem.

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 female patients between 18-65 years of age.
2. Patients with a quetelet index (QI<=weight in (kilogram)/ squire length (meters)) < 35
3. Patients requiring uncemented primary THR, suitable for the use of the Mallory Head stem
4. The individual has no clinical relevant contra indications for total hip replacement
5. The patient is diagnosed with osteoarthritis (OA) or avascular necrosis
6. The individual is physically and mentally willing and able to comply with postoperative functional evaluation and able to participate in an appropriate rehabilitation schedule.
7. Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery

Exclusion criteria

1. The patient is unwilling to cooperate with the study
2. The patient has disorders clinically relevant for total hip replacement
3. The patient is pregnant or desired to be pregnant after surgery or is using inadequate birth control
4. Patients who had or will need another joint replacement within six months.
5. Patients who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome was 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).

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):	16-01-2008
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Mallory-head Total hip
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-05-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-05-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL14527.098.06