A post market clinical follow-up study with the Optimys Stem, with initial RSA analysis

Published: 17-12-2013
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To document the initial stabilty of the Optimys stem with radiostereometric analysis in the first 30 patients, and to perform a clinical follow up of at least 150 patient treated with this implant to document the outcome.

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

Summary

ID

NL-OMON47653

Source
ToetsingOnline

Brief title
Optimys Trial

Condition

- Joint disorders

Synonym
Hip Arthroplasty, Hip replacement

Research involving
Human

Sponsors and support

Primary sponsor: Stichting SCORE
Source(s) of monetary or material Support: Mathys Medical ,Mathys Medical Ltd

Intervention

Keyword: Hip arthroplasty, RSA, Short Stem

Outcome measures

Primary outcome

For the first part of the study the initial migration measured by RSA will be

the primary outcome. For the whole PCMF the HOOS is the primary final outcome.

Secondary outcome

Additionally survival, complications and quality of life will be documented.

Study description

Background summary

One of the advantages of short-stemmed uncemented femoral components in total hip arthroplasty could be that proximal femoral bone stock is preserved by load transfer to the femoral metaphysis. Several other advantages for short stem femoral implants are coined, the natural biomechanical situation could be more easily restored and that a more tissue sparing approach can be used due to easier insertion. The design of the short stem prosthesis is based on established short stem philosophy with good clinical outcome. The implant shall combine the benefits of short stems, for instance methaphyseal anchorage, preserving of femoral bone stock, reduced stress shielding, etc., with reliability and effectiveness of standard primary total hip arthroplasties.

Study objective

To document the initial stabilty of the Optimys stem with radiostereometric analysis in the first 30 patients, and to perform a clinical follow up of at least 150 patient treated with this implant to document the outcome.

Study design

Prospective single arm follow up study with initial RSA analysis.

Study burden and risks

Risk is comparable to the standard treatment of hip arthroplasty. Burden is additional time at the follow up moments to fill in the questionnaires and additional RSA X-rays at follow up for the first 30 patients.

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

- Suffer from primary or secondary coxarthrosis.
- Be ready to participate in the follow-up examinations mentioned above
- Be between 18 and 85 years old at the time of inclusion
- Be a candidate for a primary implantation of a hip endoprosthesis
- Be expected to recover completely
- Have a BMI of 35 or less

Exclusion criteria

• Simultaneous participation in another clinical study or documentation with other orthopaedic implants of competitors.
• Suffer from the exclusion criteria: sepsis or malignant tumours.
• Have an ASA Classification > 3.
• Have a revision surgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2014
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	11-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47055.048.13