MRI scanning for soft tissue pathology after total hip arthroplasty. A feasibility study study of a selected cohort

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1) To diagnose occurrence and details (form, size, location) of cyst formation or other MRI abnormalities in patients with Ceramic-on-Polyethylene bearings; 2) To correlate these findings to the clinical status of the patient; .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Synovial and bursal disorders
Study type	Observational invasive

Summary

ID

NL-OMON38432

Source
ToetsingOnline

Brief title
MRI scanning for soft tissue pathology after total hip arthroplasty

Condition

- Synovial and bursal disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
Cyste, metalosis

Research involving
Human

Sponsors and support

Primary sponsor: Biomet inc
Source(s) of monetary or material Support: Biomet Inc

Intervention

Keyword: Arthroplasty, Hip, Sof tissue pathology

Outcome measures

Primary outcome

Main study parameter is the occurrence and details (frequency, form, size,

location) of cyst formation or other MRI abnormalities in patients with

Ceramic-on-Polyethylene bearings who theoretically are prone to cyst formation.

Secondary outcome

Kobalt and Chromium serum concentration in perspective to the cyst.

Relation of clinical outcome and cysts.

Study description

Background summary

With the more recent availability of Metal-Artifact Reducing Sequence software for Magnetic Resonance Imaging (MRI), several peer-reviewed publications have addressed the issue of Adverse tissue reactions to metal debris (ARMD) after Metal-on-Metal (MoM) hip arthroplasty (pseudotumors/cysts). These studies report a significantly higher prevalence of MoM disease compared to studies using standard follow-up (i.e. radiographs and clinical outcomes). Knowledge on MoM disease is expanding but there is still little expertise on the grading of MoM disease and on how to treat different grades of MoM disease. This carries the risk of overreacting, possibly with unnecessary surgery as a consequence. For radiologists it is especially difficult to grade small to medium MRI abnormalities with MoM arthroplasty. Currently it is not possible to classify such small deviations as being either normal or abnormal since there is no baseline information on such MRI abnormalities. We simply do not know if these minor deviations are normal reactions to hip surgery and can occur regardless of the type of implant used. To established such a baseline, a cohort of hip arthroplasty patients with another type of implant than MoM should be scanned with MARS-MRI. We therefore selected 50 patients in our clinic, part is from an existing study cohort of 200 patients from our clinic, to scan with MARS-MRI.

Study objective

1) To diagnose occurrence and details (form, size, location) of cyst formation or other MRI abnormalities in patients with Ceramic-on-Polyethylene bearings;
2) To correlate these findings to the clinical status of the patient;
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Study design

The study is designed as a cross sectional study in a cohort of 50 Ceramic on Polyethylene hip arthroplasty patients. One group of patients consists of 20 patients with a high wear rate (> 0.2mm per year) and 8-12 years follow-up. A second group of 20 patients with a high wear rate (> 0.2mm per year) and 5-8 years of follow up and a third group of 10 patients with a Ceramic-on-Polyethylene bearing at a follow-up of 2 to 5 years who have a documented history of persistent complaints, for instance pain which is not explained, by using the following diagnostic tools: clinical evaluation, plain radiographs, wound infection parameters or bone scans.

Study burden and risks

The patients will have to undergo MARS-MRI (scanning time: 35 minutes) once. Also, standardized clinical outcome scores will be completed (i.e. Harris Hip Score, Oxford hip score) which will take approximately 10 minutes per patient. The benefit for the involved patients is they will have one free MARS-MRI, providing detailed information on any cyst development. All participating patients will receive a 15 euro giftcard.

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

Unilateral, non-revised ceramic-on-polyethylene total hip arthroplasty

Exclusion criteria

Revision surgery. Bi-lateral hip prosthesis. Proven instability. Contra-indication for MRI scanning.
Infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2013

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	13-08-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL43346.015.13