Influence of exercise and rest on pseudotumors.
MRI scanning of Metal-on-Metal total hip arthroplasy.

Published: 12-10-2015
Last updated: 20-04-2024

The influence of activity level right before the MRI is made is unknown. I seems clear that more activity results in more hydrops and so results in a larger pseudotumor. The objective of this study is to investigate the possible influence of timing...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41361

Source
ToetsingOnline

Brief title
Influence of exercise and rest on pseudotumors.

Condition

- Joint disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
cyst, Pseudotumor

Research involving
Human

Sponsors and support

Primary sponsor: Sint Annaziekenhuis
Source(s) of monetary or material Support: vanuit het Kennis Centrum Orthopedie (KOG)

Intervention

Keyword: Arthroplasty, MARS-MRI, Metal-on-Metal, Pseudotumor

Outcome measures

Primary outcome

The primary study parameter is the difference of a pseudotumor size in a Metal

on Metal total hip prosthesis in correlation with activity.

Secondary outcome

The secondary parameter is the infulence of excersise on metal ion levels.

Study description

Background summary

Although Metal-on-Metal (MoM) hip arthroplasty gained huge popularity in the beginning of this century, critical reports about Adverse Reactions to Metal Debris (ARMD) were published, eventually leading to a recall of some MoM designs1, and a stop of its use in some countries due to too many questions about its value and safety. Manifestations of ARMD include the occurrence of pseudotumors, which may cause severe symptoms, can be locally destructive and might require revision surgery in a proportion of patients. Pseudotumours, defined as a peri-articular mass caused by an immunological delayed hypersensitivity response to metal particles and characterised by a lymphocyte-dominated histological pattern. These pseudotumors usualy have an intra-articular connection.
MRI is used to noninvasively detect, monitor, and quantify the (chronic) synovitis and progressive destruction of soft tissue and bone in RA (Jacobson et al 1999).

Recent pilot study on measuring volumes in pseudotumours showed that estimating pseudotumor volume in clinical practice using maximum diameter in three different planes is easily attainable, has a strong correlation with a 3D-ROI

method, and can be used for monitoring pseudotumor volume over time.

Study objective

The influence of activity level right before the MRI is made is unknown. I seems clear that more activity results in more hydrops and so results in a larger pseudotumor.
The objective of this study is to investigate the possible influence of timing of day on making of MRI. Or to be more specific, what is the influence of exercise on the outcome of pseudotumour diagnositics with MRI?

Study design

This is an observational case-control study in patients with a pseudotumor in which the characteristics of this pseudotumor are compared with imaging followin two different conditions.

Intervention

All subjects will be scanned in MRI after a period of rest. Then all subjects will perform a excersise program followed by a second MRI scan.

Study burden and risks

Time burden:
Visit 1: A questionaire is taken for current hip performance. Physical exam and information on how to use the activity sensor. Time est. 1 hour.
In the period between the first and second visit the subject will carry the activity sensor on their upper leg. Time est. 4 days, 10 hours a day.
Visit 2: Rest for 30 minutes. MRi scanning 30 minutes. Blood samples. Excersise with fysiotherapist 60 minutes. (total time est 3 hours).
Visit 3: Excersise program 20-30 minutes. MRI scanning 30 minutes. Blood samples.

Riscs:
MRI scanning: Minimal risks as standard precautions and contraindications are taken in account.
Blood samples: Minimal risk. Haematoma
Excersise program: The subjects are asked to excersise tot their own maximum tollerance. During excersise the subjects are under supervison of the fysiotherapist to minimise the risk of excersise related complaints and minimize the rist of a fall.

Contacts

Public
Sint Annaziekenhuis

Bogardeind 2
Geldrop 5664 EH
NL
Scientific
Sint Annaziekenhuis

Bogardeind 2
Geldrop 5664 EH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Metal-on-metal total hip prosthesis with proven pseudotumor on previous MRI scanning

Exclusion criteria

(previous) septic infection of the hip
Secondairy surgical intervention in the hip
Instability of the hip

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-10-2015
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	NL47661.015.14