Pseudotumors in ceramic-onpolyethylene hip prosthesis.

No registrations found.

Ethical review Not applicable

Status Pending

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON24914

Source

NTR

Health condition

Pseudotumor Ceramic-on0polyethylene Total hip arthroplasty

Sponsors and support

Primary sponsor: St Anna Hospital

Source(s) of monetary or material Support: Biomet

Intervention

Outcome measures

Primary outcome

Prevalence of pseudotumors.

Secondary outcome

Correlation of pseudotumors with serum ion levels.

Study description

Background summary

N/A

Study objective

To asses the proportion of patients with pseudotumor observerd on MARS-MRI images.

Study design

Single observation.

Intervention

Blood serum sample of Chrome and Cobalt.

Contacts

Public

St. Anna Zorggroep, P.O. Box 90 W. Weegen, van der Geldrop 5660 AB The Netherlands

Scientific

St. Anna Zorggroep, P.O. Box 90 W. Weegen, van der Geldrop 5660 AB The Netherlands

Eligibility criteria

Inclusion criteria

1. Non-revised, unilateral Mallory-Head total hip arthroplasty with a ceramic on polyethylene bearing;

2. Willing to undergo one MRI scan.

Exclusion criteria

- 1. Any hip revision surgery;
- 2. Not willing to participate.

Study design

Design

Study type: Observational non invasive

Intervention model: Parallel

Allocation: Non controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 15-02-2013

Enrollment: 50

Type: Anticipated

Ethics review

Not applicable

Application type: Not applicable

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

NTR-new NL3570 NTR-old NTR3797

Other :

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A