Large head metal-on-metal cementless total hip arthroplasty versus 28mm metal-on-polyethylene cementless total hip arthroplasty, a prospective randomized controlled trial

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Large head metal-on-metal arthroplasties show less bone mass density loss (DEXA)and higher serum metal ion concentrations. We expect equal functional scores, greater range of motion, less dislocations, fewer periprosthetic radiolucencies and...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22044

Bron
NTR

Verkorte titel
Magnum Trial

Aandoening

osteoarthritis, hip, coxartrose, total hip arthroplasty, totale heup prothese, metal-on-metal, metal-on-polyethylene, DEXA, cobalt chromium ions

Ondersteuning

Primaire sponsor: Department of Orthopaedic Surgery,
Martini Hospital, Groningen, the Netherlands;
Departments of Orthopaedic Surgery and Biomedical Engineering, University Medical Center Groningen, University of Groningen, the Netherlands
Overige ondersteuning: 1) Department of Orthopaedic Surgery

Martini Hospital, Groningen;
2) Departments of Orthopaedic Surgery and Biomedical Engineering, University Medical Center Groningen, University of Groningen;
3) Biomet Nederland, Dordrecht
4) Anna Fonds, Leiden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Bone mass density loss and serum metal ion concentrations.

Toelichting onderzoek

Achtergrond van het onderzoek

Painful osteoarthritis of the hip can be successfully treated by total hip arthroplasty. Conventional total hip prostheses consist of a 28mm metal head and a polyethylene cup (MP). Polyethylene wear debris can however lead to osteolysis, bone loss, aseptic loosening and eventually failure of the implant, especially in high demand young patients. Metal-on-metal (MM) total hip arthroplasty is an alternative to overcome polyethylene wear induced prosthetic failure. The MM wear rate is reported to be 20 to 100 times lower than conventional polyethylene wear rates. MM wear rate is also influenced by the size of the articulation and its clearance (i.e. the difference between the radius of the head and the shell): larger heads show lower wear rates provided they have a low clearance. Another advantage of larger head sizes seems to be an increased range of motion and a reduced number of dislocations. The main claim of metal-on-metal articulations is a reduction of wear and a subsequent lower incidence of periprosthetic osteolysis. Since osteolysis is implicated in the early phases of prosthetic loosening and failure, it is essential to accurately quantify periprosthetic osteolysis. Conventional radiology is not sensitive and accurate enough to detect small amounts of osteolysis. Dual energy x-ray absorptiometry (DEXA) is able to detect even small defects in the periprosthetic bone in the acetabulum. In spite of the advantages of low wear and less dislocations, metal-on-metal hip prostheses increase systemic cobalt and chromium ion concentrations. The long term effects of these ions are unknown.

The objective of this study is to conduct a randomized controlled trial to compare two cementless total hip arthroplasties: a conventional 28mm metal-on-polyethylene articulation (MP) and a metal-on-metal large head articulation (MM).

Primary outcome parameters are bone mass density and serum metal ion concentrations at 5 and 10 years follow-up.
Secondary outcome parameters are functional scores, range of motion, number of dislocations, radiographic evaluation, survival and cytokine levels (in progress). A related research project focuses on the effects of cobalt and chromium ion concentrations on osteoblast cells in vitro.
The study design and procedures are approved by the local Medical Ethical Committee (2005-42). The study will be conducted at the Department of Orthopaedic Surgery of the Martini Hospital, which is a large teaching hospital in the city of Groningen, the Netherlands. Participation in the study is voluntary and informed consent is required.

Doel van het onderzoek

Large head metal-on-metal arthroplasties show less bone mass density loss (DEXA)and higher serum metal ion concentrations. We expect equal functional scores, greater range of motion, less dislocations, fewer periprosthetic radiolucencies and increased survival with the metal-on-metal articulation.

Onderzoeksopzet

Measurements will take place preoperatively and at 6 weeks, 1 year, 5 years and 10 years postoperatively.

Onderzoeksproduct en/of interventie

Patients in the metal-on-metal group will receive a total hip arthroplasty consisting of a cementless titanium alloy acetabular component with a cobalt-chromium liner (M2a-Magnum™, Biomet) and a cobalt-chromium femoral head varying from 38 to 60mm.

Patients in the metal-on-polyethylene group will receive a total hip arthroplasty consiting of a cementless titanium alloy acetabular component (Mallory-Head®, Biomet) with a polyethylene liner and a 28mm cobalt-chromium femoral head.
In both groups the same cementless porous coated titanium alloy stem is used (Mallory-Head®).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients aged between 18 and 80 with non-inflammatory degenerative joint disease of the hip including osteoarthritis, avascular necrosis and traumatic arthritis, admitted for cementless total hip arthroplasty.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active infection

2. Revision arthroplasty

3. Marked bone loss precluding adequate fixation

4. Unwillingness of inability to follow instruction.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1341
NTR-old	NTR1399
Ander register	: MEC 2005-42
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A