Long term results of hard-on-hard ceramic bearings total hip arthroplasty

Published: 12-03-2013
Last updated: 23-04-2024

To determine whether the clinical results of ceramic bearings are as good as expected and to sort out which parameters are influencing the implant survival and complication rate. Efficacy can be measured and the treatment of patients with this type...

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON38585

Source
ToetsingOnline

Brief title
Results of a ceramic hip

Condition

- Joint disorders

Synonym
Degenerative hip disease, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Arthroplasty, Ceramics, Hip, Retrospective

Outcome measures

Primary outcome

The main endpoint of the study is the survival of the prosthesis. The prosthesis survival is otherwise described as the time between the day of the primary THA procedure and the day revision surgery is performed, measured in months.

Secondary outcome

-Radiographic signs of osteolysis in three acetabular zones according to De Lee and Charnley, and in seven femoral zones according to Gruen, signs of stress-shielding (loss of trabecular density and decreasing cortical index), prosthetic migration, fractures.

-Analysis of the reason for prosthetic failure

-Heterotopic ossification according to Brookers classification (I-IV)

-Radiographic analysis of implant positioning on AP and axial images

-Clinical performance and functional outcomes using the Harrison Hip Score (HHS), patient satisfaction in Visual Analogue Scale (VAS), the anamnestic incidence of mid thigh pain and groin pain, static and dynamic (2008 Luca et al.), pain severity during the entire period of follow-up (VAS), squeaking.

-Physical impairments of the hip: gait analysis, Trendelenburg*s sign, strength

and stability, range of motion and leg length.

Study description

Background summary

Ceramic bearing materials have shown high potential for primary Total Hip Arthroplasty (THA) in tribological studies and in vitro analyses. While clinical results with limited follow up are fluctuating, Ceramic-on-Ceramic (ConC) prostheses are considered to be a promising alternative for the conventional THA, especially in young and active patients.

Study objective

To determine whether the clinical results of ceramic bearings are as good as expected and to sort out which parameters are influencing the implant survival and complication rate. Efficacy can be measured and the treatment of patients with this type of prosthesis can be optimized.

Primary objective:
-Determination of prosthesis survival of an uncemented ConC primary THA with revision for any reason as ending point.

Secondary Objectives:
-Radiographic evaluation of an AP and axial X-ray, focused on periprosthetic bone loss; Comparison of the post-operative X-rays with X-rays at final follow up.

-Evaluation of functional outcomes and patient satisfactory using:
1. Physical examination of the hip joint
2. Harris Hip Score (HHS) questionnaires
3. Visual Analogue Scale (VAS) for patient satisfaction and pain
-Identification and analysis of adverse events
-Distillation of potential risk factors for revision
-Determine the relation between the original indication for THA and prosthesis survival

Study design

A consecutive retrospective single centre case series of all patients with a minimal follow up of two years.

Study burden and risks

The burden consists of a hospital visit that will require under an hour in time. Patients will be asked to fill in three questionnaires, two X-rays will be made en physical examination will be performed. In exchange for the time spent at filling in the questionnaires and the hospital visit, participators receive an extensive examination of their THA and its clinical performance.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who have received an uncemented 'ceramics-on-ceramics' Total Hip Arthroplasty in the ErasmusMC during the years 2000 up to and including 2010.

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	66
Type:	Anticipated

Ethics review

Not approved

Date:	12-03-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43307.078.13