Assessing the safety and performance of a hip resurfacing prosthesis compared with a conventional total hip prosthesis in relatively young males with primary arthritis; a prospective, controlled clinical study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41141

Source
ToetsingOnline

Brief title
BHR2014 study

Condition

- Joint disorders

Synonym
Arthritis of the hip, coxarthrosis, osteoarthitis

Research involving
Human

Sponsors and support

Primary sponsor: Kliniek Orthopedium
Source(s) of monetary or material Support: Kliniek Orthopedium te Delft;tevens sponsor van de studie.

Intervention

Keyword: Birmingham, hip, metal-on metal, resurfacing

Outcome measures

Primary outcome

- UCLA activity score

- Incidence of device related adverse events.

Secondary outcome

- Evaluation of overall survival of the BHR

- Evaluation of quality of life, as assessed by the EQ-5D score, the Harris Hip

Score (HHS) and the Hip disability and

- Osteoarthritis Outcome Score (HOOS) over time

- Evaluation of cobalt blood concentrations over time

- Evaluation of the acetabular component positioning by X-ray

Study description

Background summary

Since the beginning in the 1960s, total hip arthroplasty is being seen as one of the most reliable procedures and has changed the quality of life of patients with disabling osteoarthritis. In older patients the ten-year survival rate ranges from 90%-96% (Corbett, 2010). However, young, active and high-demanding patients (<60 years) have relatively disappointing results after a conventional

THA (ten year survival rates from 72%-86%). For this reason, research for better solutions for this younger and active patient category has always continued (Corbett, 2010) (Smolders J. , 2013).

The Birmingham Hip Resurfacing (BHR) prosthesis (Smith & Nephew Inc) is such a solution. The BHR is a so-called Metal-on-Metal (MoM) resurfacing prosthesis that was released in the market 15 years ago and is successfully implanted worldwide ever since. A prosthesis such as the BHR is characterized by low wear and a more accurate restoration of the anatomical situation and therefore ideal for the relative young, active patients with an end stadium of primary arthritis of the hip.

Because of the success of the BHR hip prosthesis, many orthopaedic manufacturers have developed and marketed similar prostheses. Unfortunately these prostheses appeared to be of incorrect design. Also in the Netherlands these erroneous prostheses have been implanted, including the ASR (Johnson & Johnson) and MoM total hip prosthesis (THP, Biomet) and have been implanted in high numbers. Due to the failure of these prostheses the MoM technology has received a lot of negative publicity in the Netherlands. The Dutch Orthopaedic Association (NOV) has reacted to this publicity by issuing a guideline to her members regarding the use of MoM prostheses. The advice of the NOV of January 17 2012 indicates that there is still a possibility to use MoM-prostheses, provided that they are implanted within the setting of a clinical trial that complies with GCP (see attachment I).

However, many publications and national registries, including those from England & Wales and Australia, show that the BHR is a safe and good hip prosthesis, provided that it is correctly implanted (see 2.6) with the correct indication (Murray, 2012) (Holland, 2012) (Treacy, 2011) (Matharu, 2013) . Looking at the group of demanding patients, who currently receive a traditional total hip, the BHR would perform even better (Baker, 2011). Also, the BHR is compliant with the benchmark of the National Institute for Health and Clinical Excellence (NICE); a revision level of less than ten percent after ten years for primary THP (Weegen, 2011). In a recent review (Haddad, 2011) of MoM hip implants, the BHR shows the lowest failure rates compared with other MoM implants.

In this paper (Haddad, 2011) the authors also emphasizes that the result of MoM hip resurfacing largely depends on an appropriate surgical technique and patient selection. Also, current data suggests that the correct surgical technique in an appropriate selected cohort of patients is associated with a low incidence of adverse soft-tissue reactions. High-risk factors for developing complications include small component (implant) sizes, female gender and significant anatomical variations due to for example, dysplasia, where correct positioning may be difficult. Therefore, only patients with a primary diagnosis of arthritis of the hip will be included and female patients and males with a small femoral head size will be excluded. Besides that, the

performing orthopaedic surgeon and investigator has extensive experience in resurfacing procedures with the BHR system (see 2.6). Combined with the extensive safety measures in this protocol we provide a safe and beneficial environment for the selected study patients.

With this study we compare the BHR and a conventional THP in a young and active patient group, to confirm that for this specific patient group and under favorable implantation circumstances, the BHR is a better solution regarding the post-op activity score with comparable safety.

Study objective

With this study we compare the BHR and a conventional THP in a young and active patient group, to confirm that for this specific patient group and under favorable implantation circumstances, the BHR is a better solution regarding the post-op activity score with comparable safety.

Study design

This is a non-randomized, interventional controlled study with CE marked medical devices.
In the study 2 groups are compared; one group is treated with the BHR prosthesis, the other group with a conventional uncemented THP. The groups will be followed for 10 years.
Both groups will complete 4 questionnaires pre-operatively and annualy post-up (UCLA activity score, HOOS, EQ-5D en OHS) and physical examination will be done. The incidence of any device related adverse events will be assessed.
Patients in both groups will have will have annual xrays and MARS-MRI and ultrasound imaging at 1, 5 and 10 year FU to check for any device related adverse events.
De BHR group will be followed according to the current MoM guidelines;
If a patient has any complaints which could be related to the hip or if there are any findings on the xray images further examinations will be done (Mars-MRI, utrasound) to identify any device related adverse events and to provide treatment when necessary.

Intervention

The selected patient group in this study is already qualfied for a hip replacement.
The intervention in this trail is the implantation of the BHR resrurfacing implant instead of the standard total hip replament implant.
The control group will have no interventions.

Study burden and risks

Burden:
Since only patienst are included who are in need of a hip replacement only the study specific burden is lised below:
Both groups;
- Pre-operatively and annually post-operatively patients are requested to complete 4 questionnaires.
- During the 1, 5 and 10 year post-operative visits an MRI scan and ultrasound imaging will be done to identify any
incipient adverse device effects.
BHR group:
- During the annual visits blood is drawn for determination of cobalt levels.
It is anticipated that the annual visits will take about 0,5-1 hour more than usual.
Risks (BHR group)
The related risks can be categorized into 3 categories: general surgery related, general hip replacement related and
specifically device related.
Since all patients will undergo a hip replacement anyway, only the specific device related risks are listed below:
- Adverse reactions to metal debris (ARMD)
- Peri-prosthetic aseptic lymphocyte dominated vasculitis associated lesions (ALVAL)
- Soft tisue masses (pseudotumoren)
- Avascular necrosis
- Femoral neck fractures
In the group of patients included in this study the above mentioned adverse events are rare. This specific patient group is
relatively young and are still very active and therefore have high demands on a prosthesis. The BHR prosthesis is very
wear resistant and in case a future revision is needed (due to the relatively young age a lot of patients outlive their
prosthesis) it will be much easier compared to a initial total hip prothesis (because the femoral head is left in place and no
femoral shaft is used).

No study specific risks are expected for the control group.

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

1.Male patients between 18 and 60 years of age
2.Patients requiring primary hip replacement
3.Patients with an endstage of primary arthritis of the hip
4.Patients with a femoral head * 50 mm (as measured by calibrated X-ray imaging)

Exclusion criteria

1.Patients with a BMI >35
2.Patients with infection or sepsis
3.Patients with bone stock inadequate to support the device including:
a.Patients with severe osteopenia or with a family history of severe osteoporosis or severe osteopenia
b.Patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of the femoral head (regardless
of FICAT grade)
c.Patients with multiple cysts of the femoral head (> 1cm)
4.Patients with known moderate to severe renal insufficiency
5.Patients who are immunologically suppressed with diseases such as AIDS, or patients who are receiving

corticosteroids in high doses
6.Patients with known or suspected metal sensitivity
7.Patients who are skeletally immature
8.Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
9. Patients suffering from diabetes type I or II

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2015
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Birmingham Hip Resurfacing system;SL-Plus Hip system;Synergy Hip system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-12-2014
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	23-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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	NL49266.098.14