A prospective, single arm, open label study assessing the performance and safety of the Birmingham Hip Resurfacing system in relatively young males with primary arthritis of the hip requiring hip replacement.

Published: 20-12-2013
Last updated: 23-04-2024

The primary objectives of this study are to assess the performance of the Birmingham Hip Resurfacing in young active men with large femoral heads as measured with the Oxford Hip Score (OHS) and to evaluate the safety of this device as assessed by…

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

Summary

ID

NL-OMON38532

Source
ToetsingOnline

Brief title
BHR studie

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: Onderzoek wordt gefinancierd door Orthopedium Kliniek te Delft;tevens de sponsor.

Intervention

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

Outcome measures

Primary outcome

The primary outcome measure for efficacy in this study is the Oxfrd Hip Score.

This is a common outcome measure for this type of studies as shown in

literature.

The safety outcome is defined as the 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

The Birmingham Hip Resurfacing (BHR) prosthesis (manufactured by Smith & Nephew) is a so-called Metal-on-Metal (MoM) prosthesis that was released in the market 15 years ago and is successfully implanted worldwide ever since. MoM is very durable and therefore ideal for the relative young, active patients with an end stadium of primary arthritis of the hip. These type of patients have high demands on their new hip prosthesis.
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.

However, various 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 well placed (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 emphasize that the result of MoM hip resurfacing largely depend on appropriate surgical technique and patient selection. Also, current data suggests that 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 sizes, female gender and significant anatomical variations due to for example, dysplasia, where positioning may be difficult.

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).

With this study we are aiming to confirm that the BHR is indeed a safe implant, when used in an appropriately selected patient group and when implanted with the appropriate surgical technique.
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 exceptional 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.

Study objective

The primary objectives of this study are to assess the performance of the Birmingham Hip Resurfacing in young active men with large femoral heads as measured with the Oxford Hip Score (OHS) and to evaluate the safety of this device as assessed by the incidence of complications of hip resurfacing.

Study design

This is a non-randomized, interventional study with a CE marked device. Patients are followed up to 10 years and annually x-ray images are made, physical examination is done and blodd will be drawn (to determine cobalt levels). Besides that, the patients are requested to complete 3 questionnaires annually (HOOS, EQ-5D and OHS). At 1, 5 and 10 years post-operative an MRI and utrasound imaging of the hip will be done for additional checks on device related adverse events.
In case the patients has any complaints that could be in any way related to the device or if there are any findings on the x-ray images, further assessments will be done to check for device related adverse events.

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.

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:
- During the annual visits blood is drawn for determination of cobalt levels.
- Pre-operatively and annually post-operatively patients are requested to complete 3 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.
It is anticipated that the annual visits will take about 0,5-1 hour more than usual.

Risks
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:
Risico's
- 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).

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 hip replacement, suitable for the use of the BHR system
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

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Birmingham hip resurfacing system
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	20-12-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46349.098.13