Monitoring bone defects of the femur before hip revision and bone growth after hip revision arthroplasty with DEXA, a pilot study

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Is DEXA accurate to predict bone loss of the femur before undergoing hip revision arthroplasty and provide a tool for quantification of bone loss of the femur before hip revision arthroplasty? Can DEXA be used to monitor bone remodelling after hip...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON39308

Source
ToetsingOnline

Brief title
DEXA and hip revision arthroplasty, a pilot study

Condition

- Bone disorders (excl congenital and fractures)

Synonym
hip revision arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: de Reinier de Graaf Groep zal dit onderzoek zelf financieren

Intervention

Keyword: bone remodeling, DEXA, femoral defect, hip revision arthroplasty

Outcome measures

Primary outcome

Main study parameters are bone mineral density and bone mineral content. It is expected that these DEXA results of the revised hip after 24 months will be comparable to DEXA results of the contralateral hip. Bone mineral density and bone mineral content will increase in time when DEXA scans after surgery are compared.

Secondary outcome

Not applicable

Study description

Background summary

Bone mineral density (BMD) is usually measured with Dual-Energy X-ray Absorptiometry (DEXA). DEXA can measure BMD in a reproducible, precise and accurate manner and is also preferred because of the low radiation exposure to the patient and the low costs [1, 2]. A DEXA scan measures bone mineral content in grams (BMC) and area (A) in cm2, from which BMD (g/ cm2) is calculated. Several studies used DEXA to understand the BMD and bone remodelling around prosthetic implants [1, 3-10]. These studies showed that DEXA scanning is an accurate and reproducible procedure to determine periprosthetic BMD when positioning and rotation are strictly controlled. Less is known about revision hip arthroplasty with bone impaction grafting. Histology of the bone after bone impaction grafting in hip revision surgery showed that bone remodeling is slow and that bony healing after hip revision may be less predictable compared to primairy arthroplasies [11, 12]. Also, a few studies report evaluation of the results after revision of the hip [13-19], but only Karrholm et al. [19] included measurements of BMD with DEXA in vivo. Laursen et al. [20] studied

experimental defects around acetabular components in human post mortem pelvis specimens. They concluded that DEXA scanning provides a sensitive measure of changes in BMC around cementless hemispherical metal-backed cups.
In hip revision arthroplasty with bone impaction grafting the bone defects are restored with tightly impacted morselized cancellous bone chips in combination with a cemented cup, before implantation of the new prosthesis. The allograft bone will be resorbed and new woven bone will be formed. Remodeling of this newly formed bone into its characteristic structure will lead to the biological repair of the defect site in years after the surgery [16]. Absence of balance between the resorption of the allograft bone and the formation of new bone could contribute to stem migration [21]. To monitor this balance DEXA might be a valuable tool after hip revision surgery. Also, to determine bone loss before undergoing hip revision surgery, DEXA results could be an accurate manner.
One goal of this study is to determine if DEXA is accurate predict bone loss of the femur before undergoing hip revision arthroplasty. Can a measured difference in bone loss in the femur be correlated to differences in BMD, BMC or A and in this way, provide a tool for quantification of bone loss of the femur before hip revision arthroplasty? Another goal of this study is to monitor bone remodelling after hip revision surgery.

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Study objective

Is DEXA accurate to predict bone loss of the femur before undergoing hip revision arthroplasty and provide a tool for quantification of bone loss of the femur before hip revision arthroplasty? Can DEXA be used to monitor bone remodelling after hip revision surgery?

Study design

This study is an observational pilot study, comparing the outcomes of DEXA before and after hip revision arthroplasty for the femoral component. The study contains two parts, which are both case-control studies.

1: Observational cohort study after hip revision arthroplasty
To monitor bone remodeling after hip revision arthroplasty of the femoral component, patients will be examined with DEXA and results will be compared to the results of the contralateral side and the lumbar spine.

Inclusion:
Orthopaedic Department of RdGG Hospital Delft

Procedure
First, all hip revisions with bone impaction grafting performed during last 5 years will be evaluated and patients will be selected. Second, a DEXA scan will

be made of the revised hip and results will be compared to the DEXA results of the contralateral hip to monitor bone growth at different times after hip revision arthroplasty. Also, BMD of the lumbar spine will be measured with DEXA as a control. Oxford Hip Score and Hip disability and Osteoarthritis Outcome Score (HOOS) will be used to evaluate clinical outcomes.

2: Observational cohort study before and after hip revision arthroplasty
To determine bone defects of the femur before hip revision arthroplasty with DEXA, results will be compared to results of the contralateral side as well as to results of the defect scored during surgery. Also, bone remodeling after hip revision arthroplasty will be examined with DEXA at different times after surgery.

Inclusion:
Orthopaedic Department of RdGG Hospital Delft

Procedure
Before hip revision arthroplasty, a DEXA scan will be made of both hips and of the lumbar spine. Results of the contralateral hip and the lumbar spine will be used as control.
After hip revision arthroplasty, DEXA scans will be made at 4 different moments after surgery. Totally, at 5 different moments DEXA scans will be made: 2 weeks after surgery, 3 months, 12 months and at 24 months after surgery.

All DEXA results of the revised hip postoperatively will be compared to each other to monitor bone growth around the prosthesis. The pre-operative DEXA and the scans at 3 months and at 12 months will be made twice to determine repeatability and accuracy of the DEXA results. All scans are made at moments a control visit was planned at the hospital, except for the 24 month follow up. Therefore, for each patient, only one extra visit to the hospital has to be made.
After each DEXA scan, Oxford Hip Score and Hip disability and Osteoarthritis Outcome Score (HOOS) will be used to evaluate clinical outcomes.
During hip revision arthroplasty, bone loss of the femur will be determined using the Paprosky classification [22]. The pre-operative DEXA will be used to see whether the results of the Paprosky classification are comparable to results of bone loss determined with DEXA.

Study burden and risks

This study has a low risk for participants since DEXA has a low radiation exposure. Visits of the hospital for a DEXA scan will be coupled to regular control visits as much as possible and therefore the burden to participate will be low.

The potential risks for revision hip surgery in general are:
- infection

- post-operative pain

The potential benefits for the follow-up with DEXA after hip revision surgery are:
- early detection of complication/loosening of the prosthesis

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

The hospital criteria and protocol for patients who are diagnosed for a total hip revision will be applied.
- Diminished femoral bone stock
- patients needing revision surgery
- Patient aged 18y and older

- Patient willing to participate
- No active infection
- ASA I-III

Exclusion criteria

- Patients unwilling to participate
- Mentally retarded
- Patients with sufficient bone stock
- ASA IV / V

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	28-05-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL35745.098.11