# Comparison of contamination of femoral heads and pre-processed bone chips during hip revision arthroplasty.

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Do pre-processed bone chips have lower contamination rates compared to femoral heads, morselised at the operating theatre measured at different moments during hip revision arthroplasty?

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bacterial infectious disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON32438

**Source**
ToetsingOnline

**Brief title**
Contamination of femoral heads and pre-processed bone chips

### Condition

- Bacterial infectious disorders
- Bone and joint therapeutic procedures

**Synonym**
Hip revision arthroplasty

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Netherlands Bone Bank Foundation
**Source(s) of monetary or material Support:** Netherlands Bone Bank Foundation

## Intervention

**Keyword:** bone chips, contamination, femoral head, revision hip arthroplasty

## Outcome measures

### Primary outcome

Contamination at four different moments during the operation will show the development of contamination during the operation and will also show the differences in contamination rates between pre-processed bone chips and femoral heads morselised at the operating room. Contamination is defined as bacterial growth in one or more of the media inoculated with the swab sticks, regardless of the amount of growth.

### Secondary outcome

not applicable

# Study description

### Background summary

Total joint arthroplasties (TJA) are considered as high-risk operations, especially revision procedures. A potentially devastating complication of total hip surgery is infection. Infections result in a reduced quality of life and greater physical limitations. Furthermore, the costs of hospitalisation of an infected patient are about 3.7 times higher than the costs of hospitalisation of an uninfected patient (Whitehouse, Friedman et al. 2002). The risk of infection associated with hip revision surgery is significantly higher than the risk associated with primary hip surgery. (Ridgeway, Wilson et al. 2005) (Wilson, Charlett et al. 2008).
Procedures in which biomaterials are involved have a high risk for future infectious problems, because infecting organisms adhere and grow to form a biofilm on the biomaterial surface. This biofilm protects the infecting organisms against natural host defences and antibiotic therapy and otherwise relatively low-virulent organisms become common infecting organisms (Gristina and Costerton 1985).
Transfer of bacteria from the skin of the patient or theatre personnel through

instruments and other materials to the wound area, results in intraoperative contamination (Davis, Curry et al. 1999).
The use of pre-processed, ultra clean bone chips during impaction grafting in hip revision surgery might result in a reduction of bacterial contamination.
For defect reconstruction in hip revision surgery, allograft cancellous bone is used. This allogeneic bone can be fresh frozen total femoral head or pre-processed bone chips. The preparation of bone chips for impaction grafting at the operating theatre is a procedure which involves more instruments and personnel compared to the use of pre-processed bone chips. Mostly, the preparation of these bone chips in the operating theatre takes place outside the plenum and takes for about ten minutes. Pre-processed bone chips are prepared at a clean room at the bone bank. During this preparation, cultures are taken of the bone chips and allografts with a positive culture are discarded. As a result of the possible reduction in contamination, infection rates might also decrease. Furthermore, time for preparation of the bone chips is reduced, since morselising the femoral head and rinsing the bone chips is not necessary, sparing expensive operation theatre time. Costs of these pre-processed bone chips are higher compared to the costs of a femoral head. Therefore, the advantages of the pre-processed bone chips have to be shown.

### Study objective

Do pre-processed bone chips have lower contamination rates compared to femoral heads, morselised at the operating theatre measured at different moments during hip revision arthroplasty?

### Study design

The study is a prospective randomised trial comparing the outcomes between bacterial contamination of pre-processed bone chips and femoral heads morselised at the operating room.

### Intervention

Two groups will receive either pre-processed bone chips or a femoral head, morselized at the operating room. Contamination rates will be measured by swabbing the bone surface.

### Study burden and risks

The normal ad standard potential risks and benefits are clinical relevant in the trial.
The potential risks for revision hip surgery in general are:
- infection
- post-operative pain

The potential benefits for the use of pre-processed bone chips during the operation are:
- reduced chance of infection
- reduction of operation time

# 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 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
- Patients with sufficient bone stock
-Mentally retarded
-ASA IV / V

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

**Primary purpose:** Prevention

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2009 |
| Enrollment: | 88 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 29-09-2008 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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 | NL23991.098.08 |