

# Prospective randomised clinical trial comparing hip resurfacing and cementless metal-on-metal total hip arthroplasty

<b>Submission date</b> 11/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/04/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Osteoarthritis is a condition where the cartilage inside the hip joint becomes worn away, leading to the bones rubbing against each other and becoming damaged. There are several different types of surgery available for osteoarthritis. A total hip arthroplasty involves replacing the damaged hip joint with an artificial one. Hip resurfacing replaces just the diseased or damaged surfaces in the hip joint with metal implants - less bone is removed than if you have total hip arthroplasty. The aim of this study is to compare patient outcomes after hip resurfacing and cementless metal-on-metal total hip arthroplasty.

### Who can participate?

Patients aged 18 to 60 with primary osteoarthritis of the hip

### What does the study involve?

Participants are randomly allocated to undergo either cementless metal-on-metal total hip arthroplasty or hip resurfacing. Participants attend follow-up visits 2, 5 and 10 years later, where they undergo walking tests and pain, discomfort, osteoarthritis symptoms and quality of life are assessed.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Helsinki University Central Hospital (Finland)

### When is the study starting and how long is it expected to run for?

November 2006 to December 2016

### Who is funding the study?

1. Helsinki University Central Hospital (Finland)
2. Orion-Farmos Research Foundation (Finland)

Who is the main contact?

Dr Ville Remes  
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## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00570167

Secondary identifying numbers

TYH7306

## Study information

### Scientific Title

Prospective randomised clinical trial comparing hip resurfacing and cementless metal-on-metal total hip arthroplasty

### Study objectives

To compare clinical, functional and radiological outcome after hip resurfacing and cementless metal-on-metal total hip arthroplasty.

### Ethics approval required

Old ethics approval format

Ethics approval(s)

**Study design**

Prospective randomised clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Hip osteoarthritis

**Interventions**

Cementless metal-on-metal total hip arthroplasty (Birmingham Hip Resurfacing arthroplasty [BHR]-Synergy) versus hip resurfacing (BHR). Follow-up visits will be at 2, 5 and 10 years.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Pain and discomfort on Visual Analogue Score (VAS) scale and in 7-point Likert-scale, measured at 2, 5 and 10 years

**Secondary outcome measures**

1. A difference of 15 points in the Western Ontario and McMaster Universities Osteoarthritic Index (WOMAC) questionnaire, converted to a scale of 0 to 100, measured at 2, 5 and 10 years
2. Difference in indicators of functional capacity (20-metre walking test and 3-metre "up and go" test), measured at 2, 5 and 10 years
3. Difference in the observed change in the quality of life, measured at 2, 5 and 10 years
4. Difference in the observed cost-effectiveness, measured at 2, 5 and 10 years

**Overall study start date**

30/11/2006

**Completion date**

31/12/2016

# Eligibility

## Key inclusion criteria

1. Primary osteoarthritis of the hip, planned to be treated by hip replacement surgery
2. Normal acetabulum, or no more than mild dysplasia of the acetabulum
3. Aged 18 to 60 years
4. The patient's mother tongue is Finnish

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

142

## Key exclusion criteria

1. Patient has a secondary osteoarthritis of hip
2. The patient has undergone endoprosthetic surgery of the other hip in the preceding six months, or such a procedure is planned for the patient in the next six months
3. The patient has undergone or is planned to undergo endoprosthetic surgery of the knee or ankle in the next year
4. The patient has undergone surgery of the other hip, knee or ankle with an unsatisfactory outcome
5. The patient has been diagnosed with or is suspected to have an untreated or recurring malignancy or systemic infection
6. A disease treated with cortisone or immunosuppressive medication
7. The patient's cooperation is impaired for any reason
8. Any systemic disease that impairs the patient's mobility
9. Female patients in fertile age who are planning to have children during the study
10. The patient has previously undergone an operation of the hip region that extended below the subcutaneous tissue
11. The patient has experienced a femoral neck fracture
12. The patient has been diagnosed with or is strongly suspected to have osteoporosis (T-score less than or equal to -2.5 SD)
13. The patient has a systemic or metabolic disease that has impaired or is going to impair bone quality
14. A significant cyst (diameter greater than 1 cm) or cysts in the area of the femoral neck
15. Bilateral simultaneous hip arthroplasty
16. Neck-shaft angle 120 degrees or less
17. Deformed femoral head making hip resurfacing impossible
18. Head-neck ratio less than 1.2
19. Avascular necrosis of the femoral head

**Date of first enrolment**

30/11/2006

**Date of final enrolment**

31/12/2016

## **Locations**

**Countries of recruitment**

Finland

**Study participating centre**

**Helsinki University Central Hospital**

Helsinki

Finland

FIN-00029

## **Sponsor information**

**Organisation**

Helsinki University Central Hospital (Finland)

**Sponsor details**

Surgical Hospital

P.O. Box 263

Helsinki

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FIN-00029

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.hus.fi>

**ROR**

<https://ror.org/02e8hzf44>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Helsingin ja Uudenmaan Sairaanhoidopiiri

**Alternative Name(s)**

Helsinki University Central Hospital, HUS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Finland

**Funder Name**

Orion-Farmos Research Foundation (Finland)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration