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

Submission date
11/05/2007

Recruitment status
No longer recruiting

Registration date
12/09/2007

Overall study status
Completed

Last Edited
15/04/2019

Condition category
Musculoskeletal Diseases

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] 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?
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Contact information

Type(s)
Scientific

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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)

Ethical committee of Surgical Department, Turku University Central Hospital, 02/05/2006, ref: TEKOHeKuTu2006/11032006

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 McMasters 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
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FIN-00029

Sponsor information

Organisation
Helsinki University Central Hospital (Finland)

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Surgical Hospital
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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 Sairaanhoitopiiri

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