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Comparing total hip arthroplasty and hemi-arthroplasty on revision surgery and quality of life in adults with displaced hip fractures: the HEALTH study

Submission date
08/09/2009

Recruitment status
No longer recruiting

Registration date
18/09/2009

Overall study status
Completed

Last Edited
23/05/2022

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00556842

Protocol serial number
MCT-90168

Study information

Scientific Title
Hip fracture Evaluation with ALternatives of Total Hip arthroplasty versus hemi-arthroplasty (HEALTH): a multicentre randomised trial comparing total hip arthroplasty and hemi-arthroplasty on revision surgery and quality of life in patients with displaced femoral neck fractures

Acronym
HEALTH

Study objectives
We hypothesise that total hip arthroplasty will have similar or lower rates of revision surgery and higher functional outcome scores at 24 months compared with hemi-arthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Canada: Hamilton Health Sciences Research Ethics Board approved on the 20th May 2008 (ref: 06-151)
2. Netherlands: Medical Research Ethics Committee approved on the 14th October 2008 (ref: NL12833.078.06 [local nr MEC-2006-182])
3. USA: Institutional Review Board of Boston University Medical Campus approved on the 12th May 2008 (ref: H-27108)

Study design
Interventional treatment randomised double-blind (subject, outcomes assessor) parallel assignment multicentre efficacy study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip Fractures (displaced femoral neck fractures)

Interventions
Total hip arthroplasty versus hemi-arthroplasty. Patient followed for 2 years post-operatively.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Revision surgery, measured 2 years after original surgery

Key secondary outcome(s))
1. Function, measured 2 years after original surgery using Western Ontario McMaster Osteoarthritis Index (WOMAC) and Timed Up and Go Test (TUG) administered at 1, 2, 10 weeks, and 6, 9, 12, 18, 24 months
2. Complications, including mortality, dislocation, infection, femoral fracture, deep venous thrombosis, and prosthesis loosening, measured 2 years after original surgery
3. Quality of life, measured 2 years after original surgery using 12-item short form health survey (SF-12) and EuroQoL (EQ-5D) administered at 1, 2, 10 weeks, and 6, 9, 12, 18, 24 months

Completion date
30/03/2012

Eligibility

Key inclusion criteria
1. Adult men or women aged 50 years and older (with no upper age limit)
2. Fracture of the femoral neck confirmed with either anteroposterior or lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI)
3. Displaced fracture that is not, in the judgment of the attending surgeon, optimally managed by reduction and internal fixation
4. Operative treatment within 3 days (i.e. 72 hours) of the patient being medically cleared for surgery
5. Patient was ambulatory prior to fracture, though they may have used an aid such as a cane or a walker
6. Anticipated medical optimization for arthroplasty of the hip
7. Provision of informed consent by patient or proxy
8. Low energy fracture (defined as a fall from standing height)
9. No other major trauma
10. Assurance that surgeons with expertise in both total hip arthroplasty and hemiarthroplasty are available to perform surgery. Note: Surgeons do not need to be experts in both techniques.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Patient not suitable for arthroplasty (e.g. inflammatory arthritis, rheumatoid arthritis, pathologic fracture (secondary to cancer), or severe osteoarthritis of the hip)
2. Associated major injuries of the lower extremity (i.e., ipsilateral or contralateral fractures of the foot, ankle, tibia, fibula, knee, or femur; dislocations of the ankle, knee, or hip; or femoral head defects or fracture)
3. Retained hardware around the affected hip that will interfere with arthroplasty

4. Infection around the hip (soft tissue or bone)
5. Patients with a disorder of bone metabolism other than osteoporosis (i.e., Paget's disease, renal osteodystrophy, osteomalacia)
6. Patients with a previous history of frank dementia that would interfere with assessment of the primary outcome (i.e., revision surgery at 2 years)
7. Likely problems, in the judgment of the investigators, with maintaining follow-up (i.e., patients with no fixed address, report a plan to move out of town, or intellectually challenged patients without adequate family support)
8. Attending surgeon believes the patient should be excluded because enrolled in another ongoing drug or surgical intervention trial
9. Any other reason

Date of first enrolment
01/03/2009

Date of final enrolment
30/03/2012

Locations

Countries of recruitment
Canada

Netherlands

United States of America

Study participating centre
CLARITY Orthopaedic Research
Hamilton
Canada
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Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type

Research organisation

Funder Name
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (USA)

Alternative Name(s)
The National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Arthritis & Musculoskeletal & Skin Diseases, Instituto Nacional de Artritis y Enfermedades Musculoesqueléticas y de la Piel, NIAMS

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Funder Name
Hamilton Health Sciences (Canada)

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-90168)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/02/2015		Yes	No

Basic results	Study website	07/07/2020	23/05/2022	No	No
Study website		11/11/2025	11/11/2025	No	Yes