A Multi-Centre Randomized Trial Comparing Total Hip Arthroplasty and Hemi-Arthroplasty on Secondary Procedures and Quality of Life in Patients with Displaced Femoral Neck Fractures

Published: 07-08-2015
Last updated: 19-04-2024

The primary objective is to assess the impact of total hip arthroplasty versus hemi-arthroplasty on rates of secondary procedures at 2 years in individuals with displaced femoral neck fractures.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON42587

Source
ToetsingOnline

Brief title
HEALTH

Condition

- Bone and joint therapeutic procedures

Synonym
Femoral Neck Fractures

Research involving

Human

Sponsors and support

Primary sponsor: McMaster University
Source(s) of monetary or material Support: Canadian Institutes of Health Research

Intervention

Keyword: Hemi-Arthroplasty, Hip fracture, Total Hip Arthroplasty

Outcome measures

Primary outcome

The primary outcome is any unplanned secondary procedure within 2 years of the

initial joint replacement surgery.

Secondary outcome

Secondary outcomes will include:

Functional outcome

quality of life

mortality

hip-related complications.

Study description

Background summary

This is a multi-centre, blinded,randomized control trial to evaluate two alternative approaches (total hip arthroplasty and hemiarthroplasty) for treating displaced femoral neck fractures in elderly patients. Although current opinion among orthopaedic surgeons favours the use of arthroplasty for displaced femoral neck fractures, there is lack of agreement on which type of arthroplasty is optimal. The rationale for this study is driven by: 1) the high incidence and serious consequences of hip fractures; 2) the orthopaedic community*s uncertainty about the optimal type of arthroplasty; 3) a feasible and efficient study design; and 4) extensive

support for the trial.

Study objective

The primary objective is to assess the impact of total hip arthroplasty versus hemi-arthroplasty on rates of secondary procedures at 2 years in individuals with displaced femoral neck fractures.

Study design

HEALTH is a multi-centre, concealed *expertise-based* randomized trial design using minimization to determine patient allocation. Surgeons across North America, Europe, Asia, and Australia will participate. Patients who have sustained a displaced femoral neck fracture will be randomized to one of two surgical interventions. The first surgical intervention involves total hip arthroplasty (i.e., replacement of the femoral head and hip socket). The second surgical intervention involves a hemi-arthroplasty (i.e., replacement of the femoral head only). Each participating site will have on staff surgeons with expertise in both interventions to ensure adherence to the expertise-based design. Study personnel will monitor critical aspects of peri-operative care and rehabilitation. We will assess patients at hospital admission (baseline), 1 week, 10 weeks, 6 months, 9 months, 12 months, 18 months, and 24 months after surgery. Fracture eligibility when in doubt, technical placement of prostheses, secondary procedures, fracture-related complications, and deaths will be independently adjudicated.

Intervention

A total hip arthroplasty versus a hemi-arthroplasty

Study burden and risks

The patient will need about 2 hours to complete the questionnaires. Also, two extra radiographs will be made.

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

1. Aged 65 years or older.
2. Have a femoral neck fracture confirmed with anteroposterior (AP) and/or lateral hip radiographs, or computed tomography (CT), or magnetic resonance imaging (MRI).
3. Have a displaced fracture that is not repairable via reduction and internal fixation in the judgment of the attending surgeon
4. The operative treatment will take place within 3 days (i.e. 72 hours) of the patient being medically cleared for surgery.
5. Be ambulatory prior to fracture, though they may have used an aid.
6. Have anticipated medical optimization for arthroplasty of the hip (i.e. patient is cleared for surgery).
7. Provides informed consent
8. Have a low energy fracture (defined as a fall from standing height).
9. Have no other major trauma (defined as an Injury Severity Score <17)
10. Surgeons with expertise in both THA and HA are available to perform the surgery

Exclusion criteria

1. The patient is not suitable for hemi*arthroplasty (e.g., inflammatory arthritis, rheumatoid arthritis, pathologic fracture [secondary to cancer], or severe

osteoarthritis of the hip).
2. The patient has associated major injuries of the lower extremity (e.g. 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. The patient has retained hardware around the affected hip that will interfere with arthroplasty.
4. The patient has a soft tissue or bone infection around the hip.
5. The patient has a bone metabolism disorder other than osteoporosis (e.g., Paget*s disease, renal osteodystrophy, osteomalacia).
6. The patient has a previous history of frank dementia that would interfere with assessment of the primary outcome (i.e. revision surgery at 2 years).
7. There may be problems with maintaining follow*up (e.g., patients with no fixed address, report a plan to move out of town, or intellectually challenged patients without adequate family support), in the judgment of the attending surgeon.
8. The fracture occurred as a result of an act of violence.
9. The patient is participating in another ongoing drug or surgical intervention trial.
10. The attending surgeon believes that there is another reason to exclude the patient.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2015
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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
Other	clinical trials.gov
CCMO	NL52941.075.15

Study results