Hip Fracture Evaluation with ALternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH): A Multi-Centre Randomized Trial Comparing Total Hip Arthroplasty and Hemi-Arthroplasty on Revision Surgery and Quality of Life in Patients with Displaced Femoral Neck Fractures

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In patients over 60 years of age who have sustained a displaced femoral neck fracture, what is the rate of revision surgery at 24 months when a total hip arthroplasty versus hemi-arthroplasty is used as the surgical treatment? Hypothesis: We...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON35128

Source
ToetsingOnline

Brief title
HEALTH

Condition

- Fractures

Synonym
broken hip, hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: femoral neck fracture, hemiarthroplasty, randomized trial, total hip arthroplasty

Outcome measures

Primary outcome

The primary outcome is revision surgery within 2 years of surgery.

Secondary outcome

The secondary outcomes include health-related quality of life (Short Form-12,

SF-12), functional outcomes (Western Ontario McMaster Osteoarthritis Index,

WOMAC), and health utility (Health Utilities Index Mark III, HUI3). We will

independently adjudicate revision surgery rates at regular intervals up to 2

years.

Study description

Background summary

Hip fractures are associated with a 30% mortality rate and profound temporary and sometimes permanent impairment of independence and quality of life. Worldwide, 4.5 million persons are disabled from hip fractures yearly with an expected increase to 21 million persons living with disability in the next 40 years.
Hip fractures occur in 280,000 Americans (over 5,000 per week) and 36,000 Canadians (over 690 per week) annually. The number of hip fractures is likely

to exceed 500,000 annually in the United States and 88,000 in Canada. The estimated annual health care costs will reach a staggering $9.8 billion in the United States and $650 million in Canada.
Hip fractures occur in 18.000 Dutch citizens annually.
Advocates of hemi-arthroplasty focus upon reduced dislocation rates, lower rates of deep vein thrombosis, shorter operating times, less blood loss, and a technically less demanding procedure. Surgeons supporting total hip arthroplasty perceive benefits in improving patient function and improving quality of life. Methodological limitations of previous studies, as well as their small sample sizes and resulting wide confidence intervals, have left the optimal operative approach unresolved.

Study objective

In patients over 60 years of age who have sustained a displaced femoral neck fracture, what is the rate of revision surgery at 24 months when a total hip arthroplasty versus hemi-arthroplasty is used as the surgical treatment?
Hypothesis: We hypothesize that total hip arthroplasty will have similar or lower rates of revision surgery (primary outcome) and higher functional outcome scores (secondary outcome) at 24 months compared with hemi-arthroplasty.

Study design

We propose a multi-centre, concealed *expertise-based* randomized trial design using minimization to determine patient allocation. In conventional surgical hip fracture trials, all surgeons involved in the trial have performed both total hip arthroplasties and hemi-arthroplasties based on the randomization process. We propose an alternative randomized trial design that allocates patients to surgeons with expertise in total hip arthroplasty who are committed to performing only total hip arthroplasty, or to surgeons with expertise in hemi-arthroplasty who are committed to performing only hemi-arthroplasty. Based upon their expertise, surgeons will use one of two surgical strategies in patients who have sustained a displaced femoral neck fracture. The first strategy involves total hip arthroplasty (i.e., replacement of the femoral head and hip socket). The second treatment strategy involves a hemi-arthroplasty (i.e., replacement of the femoral head only). Study personnel will monitor critical aspects of peri-operative care and rehabilitation for protocol deviations.

Potential Impact of Study: this trial will not only change current orthopaedic practice, but will set a benchmark for the conduct of future orthopaedic trials.

Intervention

Hemiarthroplasty versus Total Hip Arthroplasty

Study burden and risks

Surgeons worldwide are currently using both surgical techniques (i.e., total hip arthroplasties and hemi-arthroplasties). Arthroplasty has been used for over 5 decades in the management of displaced femoral neck fractures. Arthroplasty procedures (as with any surgical procedure of the lower extremity) have potential risks that include wound infection, DVT, neurovascular injury, compartment syndrome, and death. All patients eligible for the trial; however, require surgical treatment. We will monitor all adverse events following treatment across both arms. Our independent Data Monitoring Committee (DMC) and Data Safety and management Committee (DSMC) will review this information at regular intervals.

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. Adult men or women aged 60 years and older (with no upper age limit).
2. Fracture of the femoral neck confirmed with either anteroposterior or lateral hip radiographs.
3. Displaced fracture in the judgment of the attending surgeon.
4. Operative treatment within 3 days (i.e., 72 hours) of presenting to the emergency room.
5. Provision of informed consent by patient or legal guardian.
6. No other major trauma to ipsi- or contralateral extremity.

Exclusion criteria

1. Patient not suitable for hemi-arthroplasty (i.e., inflammatory arthritis, rheumatoid arthritis, pathologic fractures, 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.
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. Moderate or severe cognitively impaired patients (i.e., Six Item Screener with 3 or more errors).
7. Patients with Parkinson*s disease (or dementia) severe enough to increase the likelihood of falling or severe enough to compromise rehabilitation.

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):	11-10-2006
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	11-09-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-10-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25934
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL12833.078.06