Hip Fracture Evaluation with ALternatives of Total Hip Arthroplasty versus Hemi-Arthroplasty (HEALTH).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25934

Source
Nationaal Trial Register

Brief title
HEALTH

Health condition

Displaced femoral fracture

Sponsors and support

Primary sponsor: IHFRC
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Revision surgery within 2 years of initial surgery to promote fracture healing, relieve pain, treat infection, treat a peri-prosthetic fracture, or improve function include the following:

1. Reduction of hip dislocation;

2. Revision surgery with another implant;

3. Incision and drainage for any infection;

4. Implant exchange or removal.

Secondary outcome

1. Functional outcome score (WOMAC);

2. Functional mobility score (TUG);

3. Quality of life (SF-12, EQ-5D);

4. Cost-utility ratio (using Health-care consumption questionnaire);

5. Complication rate, including mortality, implant breakage or failure, peri-prosthetic fracture, and infection (i.e., superficial and deep).

Study description

Background summary

Rationale:

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 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. 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.

Objective:

In patients over 50 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 hemiarthroplasty is used as the surgical treatment?

Hypothesis:

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. Total hip replacement will be a cost-effective intervention.

Study Design:

Multi-centre, concealed ‘expertise-based’ randomized trial design using minimization to determine patient allocation. Surgeons across North America, South America, Europe, Australia, Asia, and Africa will participate. In conventional surgical hip fracture trials, all surgeons involved in the trial have performed both total hip arthroplasties and hemiarthroplasties 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 hemiarthroplasty 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. The primary clinical outcome measure is revision surgery within 2 years of surgery. The primary health-economic outcome measure is the Cost-utility ratio of total hip arthroplasty versus hemi-arthroplasty. The secondary outcomes include healthrelated quality of life (Short Form-12, SF-12), functional outcomes and mobility (Western Ontario McMaster Osteoarthritis Index, WOMAC, and Timed Up and Go test, TUG), and health outcomes measure (EuroQol-5D, EQ-5D). Data will be collected at hospital admission (baseline), 1 week, 2 weeks, 10 weeks, 6 months, 9 months, 12 months, 18 months, and 24 months after surgery. Revision surgery rates will be independently adjudicated.

Study objective

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

Baseline, Surgery, 1 week, 2 weeks, 10 weeks, 6 months, 9 months, 12 months, 18 months, 24 months.

Intervention

1. Total hip replacement;

2. Hemi-arthroplasty.

Contacts

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Eligibility criteria

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 in the judgment of the attending surgeon;

4. Operative treatment within 3 days (i.e., 72 hours) of presenting to the emergency room;

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.

Exclusion criteria

1. Patient not suitable for 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., Mini-Mental Status Examination (MMSE) 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;

8. 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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2008
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	12-01-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35128
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL685
NTR-old	NTR1623
CCMO	NL12833.078.06
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON35128

Study results

Summary results
Burgers PTPW, Poolman RW, Culgin S, Einhorn TA, Bhandari M, Patka P, Van Lieshout EMM, namens de HEALTH trial onderzoekers. Centrale coördinatie van een multicenter studie als alternatief voor betaling per patiënt: de ervaring bij de HEALTH-trial. Ned Tijdschr Traum 2012;20(1):2-8.

Bhandari M, Devereaux PJ, Einhorn TA, Thabane L, Schemitsch EH, Koval KJ, Frihagen F, Poolman RW, Tetsworth K, Guerra-Farfán E, Madden K, Sprague S, Guyatt G; HEALTH Investigators.

Hip fracture evaluation with alternatives of total hip arthroplasty versus hemiarthroplasty (HEALTH): protocol for a multicentre randomised trial.

BMJ Open. 2015 Feb 13;5(2):e006263.

Burgers PTPW, Poolman RW, Van Bakel TMJ, Tuinebreijer WE, Zielinski SM, Bhandari M, Patka P, Van Lieshout EMM, on behalf of the HEALTH and FAITH trial investigators.

Reliability, Validity, and Responsiveness of the Western Ontario and McMaster Universities Osteoarthritis Index for Elderly Patients with a Femoral Neck Fracture.

J Bone Joint Surg Am. 2015 May 6;97(9):751-757.