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Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH): a multi-centre randomised trial comparing sliding hip screws and cancellous screws on revision surgery rates and quality of life in the treatment of femoral neck fractures

Submission date
13/06/2008

Recruitment status
No longer recruiting

Registration date
13/06/2008

Overall study status
Completed

Last Edited
21/10/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ihfrc.ca

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00761813

Secondary identifying numbers
MCT-87771

Study information

Scientific Title
Fixation using Alternative Implants for the Treatment of Hip fractures (FAITH): a multi-centre randomised trial comparing sliding hip screws and cancellous screws on revision surgery rates and quality of life in the treatment of femoral neck fractures

Acronym
FAITH

Study objectives
We hypothesise that sliding hip screws will have lower rates of revision surgery (primary outcome) and higher functional outcome scores (secondary outcome) compared with cancellous screws.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Research Ethics Board of McMaster University on the 23rd November 2006 (ref: 06-402).

Study design
Single blind (study participant, outcome assessor, data analyst, adjudication committee), randomised trial using minimisation

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
Femoral neck fractures

Interventions
Sliding hip screw fixation versus multiple cancellous screw fixation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Revisions surgery as measured at 12 months.

Secondary outcome measures
1. Health related quality of life (12-item short form health survey [SF-12]), measured post-operatively at 1 week, 2 weeks, 3 months, 6 months, 9 months and 12 months
2. Functional outcomes (Western Ontario and McMaster Osteoarthritis Index [WOMAC]), measured post-operatively at 1 week, 2 weeks, 3 months, 6 months, 9 months and 12 months
3. Health outcomes (European quality of life instrument [EQ-5D]), measured post-operatively at 1 week, 2 weeks, 3 months, 6 months, 9 months and 12 months
4. Complications, including mortality, avascular necrosis, non-union, implant breakage or failure, and infection (i.e., superficial and deep). Measured post-operatively at 1 week, 2 weeks, 3 months, 6 months, 9 months and 12 months.

Overall study start date
01/06/2008

Completion date
01/01/2010

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 and lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI)
3. Any degree of displacement (i.e., undisplaced or displaced) of the femoral neck fracture that can be closed reduced
4. Operative treatment of displaced fractures within two days (i.e., 48 hours) of presenting to the emergency room
5. Operative treatment of undisplaced fractures within 7 days of presenting to the emergency room
6. Patient was ambulatory prior to fracture, though they may have used an aid such as a cane or a walker

7. Anticipated medical optimalisation for operative fixation of the hip
8. Provision of informed consent by patient or legal guardian
9. No other major trauma
10. Low energy fracture (defined as a fall from standing height)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Total final enrolment
1108

Key exclusion criteria
1. Patients not suitable for internal fixation (i.e., severe osteoarthritis, rheumatoid arthritis, or pathologic fracture)
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 (i.e., soft tissue or bone)
5. Patients with disorders of bone metabolism except osteoporosis (i.e., Paget's disease, renal osteodystrophy, osteomalacia)
6. Moderate or severe cognitively impaired patients (i.e., Mini-Mental State 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)

Date of first enrolment
01/06/2008

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Canada

Study participating centre
McMaster University
Hamilton, Ontario
Canada
L8L 8E7

Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor type
University/education

Website
http://www.mcmaster.ca/

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-87771)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	design and rationale	26/06/2014	21/10/2019	Yes	No
Results article	preplanned secondary analysis results	16/10/2019	21/10/2019	Yes	No
Results article	results	01/04/2017	21/10/2019	Yes	No