

# 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

<b>Submission date</b> 13/06/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/10/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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)

NCT00761813

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

Revisions surgery as measured at 12 months.

### **Key secondary outcome(s)**

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.

### **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 optimisation 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

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## **Sponsor information**

### **Organisation**

McMaster University (Canada)

### **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

## 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?
<a href="#">Results article</a>	preplanned secondary analysis results	16/10/2019	21/10/2019	Yes	No
<a href="#">Results article</a>	results	01/04/2017	21/10/2019	Yes	No
<a href="#">Other publications</a>	design and rationale	26/06/2014	21/10/2019	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes