Fixation using Alternative Implants for the Treatment of Hip Fractures.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25279

Bron
NTR

Verkorte titel
FAITH

Aandoening

Femoral neck fracture.

Ondersteuning

Primaire sponsor: IHFRC (www.ihfrc.ca)
Stichting Nuts-Ohra
Overige ondersteuning: Stichting Nuts-Ohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the impact of sliding hip screws versus cannulated screw fixation on rates of

revision surgery at 2 years in individuals with femoral neck fractures.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY OF RESEARCH PROPOSAL

Rationale

Hip fractures occur in 280,000 Americans (over 5000 per week) and 36,000 (over ? per week) Canadians 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. Experimental data suggest that cancellous screws offer greater preservation of blood and supply, while sliding hip screws provide greater biomechanical stability to bending stresses. While both arguments are persuasive, the impacts of these biologic alterations on outcomes that are important to patients offer more compelling guidance for clinical practice

Need for a Definitive RCT

We summarize the rationale for the trial below. First, although current opinion among orthopaedic surgeons favors the use of cancellous screws over sliding hip screws, there remains sufficient divergence in perceptions and sufficient interest to resolve this issue to warrant a large RCT. Second, despite the popularity of cancellous screw fixation, there is a strong biologic rationale supporting the sliding hip screws, a more biomechanically stable construct, in older patients with osteopenia/osteoporosis. Third, while our meta-analyses provide indirect and direct evidence that a sliding hip screw may revision surgery rates, the evidence remains far from definitive. The current best estimate of treatment effect with sliding hip screws is based upon small trials with methodologic limitations including unconcealed randomization and lack of blinding. The resulting estimates include wide confidence intervals (i.e., displaced fractures: RRR=27%, 95%CI: 48%, -4%, P=0.08 and 4). Whatever approach to internal fixation proves best, a large proportion of patients will continue to need revision surgery that is associated with high morbidity and appreciable

mortality.

Objective

To assess the impact of sliding hip screws versus cannulated screw fixation on rates of revision surgery at 2 years in individuals with femoral neck fractures. We secondarily aim to determine the impact on 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).

Hypothesis

We hypothesize that sliding hip screws will have lower rates of revision surgery (primary outcome) and higher functional outcome scores (secondary outcome) at 24 months compared with cancellous screws.

Study Design

We propose a multi-centre, concealed randomized trial design using minimization to determine patient allocation. Surgeons across Canada, United States, South America, Europe, Australia, and Asia will participate. Surgeons will use one of two surgical strategies in 2,500 patients who have sustained a femoral neck fracture. The first strategy involves fixation of the fracture with multiple small diameter cancellous screws (i.e., Cancellous Screw Group). The second treatment strategy involves fixation of the fracture with a single larger diameter screw with a sideplate (i.e., Sliding Hip Screw Group). Study personnel will monitor critical aspects of peri-operative care and rehabilitation for protocol deviations. We will independently adjudicate revision surgery rates at discharge, 2 weeks, 10 weeks, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months post surgery. The primary outcome is revision surgery within 2 years of surgery. The secondary outcomes include patient quality of life (Short Form-12, SF-12), function (Western Ontario McMaster Osteoarthritis Index, WOMAC), and health utility (Health Utilities Index Mark III, HUI3). We will independently adjudicate revison surgery rates at regular intervals up to 2 years.

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.

Doel van het onderzoek

We hypothesize that sliding hip screws will have lower rates of revision surgery (primary outcome) and higher functional outcome scores (secondary outcome) at 24 months compared with cancellous screws.

Onderzoeksopzet

Baseline, operation, 2 and 8 weeks, 6-9-12-18-24 months.

Onderzoeksproduct en/of interventie

1. Internal Fixation;

2. DHS versus cannulated screws.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 or computed tomography, or magnetic resonance imaging;

3. Any degree of displacement (i.e., undisplaced or displaced) of the femoral neck fracture that can be close reduced;

4. Operative treatment of displaced fractures within 2 days (i.e., 48 hours) of presenting to the emergency room;

5. Operative treatment of undisplaced fractures within 7 days;

6. Patients was an ambulatory, though they may have used an aid such as a cane or a walker, prior to fracture;

7. Anticipated medical optimalization for operative fixation of the hip by anesthesia and/or internal medicine team;

8. Provision of informed consent by patient or legal guardian;

9. Low energy fracture (defined as a fall from standing height), with no other major trauma.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patinet not suitable for internal fixation (i.e., severe osteoarthritis, rheumatoid arthritis, pathologic fracture);

2. Associated injuries of the lower extremity (i.e., ipsilateral or contralateral fractures of the femoral shaft, tibia, or foot, femoral head defects or fracture, or hip dislocation);

3. Retained hardware around the affected hip;

4. Infection around the hip (soft tissue or bone);

5. Patients with disorders of bone metabolism other than osteoporosis (i.e., Paget’s disease, renal osteodystrophy);

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;

Likely problems, in the judgment of the investigators, with maintaining follow-up. We will, for example, exclude patients with no fixed address, those who report a plan to move out of town in the next year, or intellectually challenged patients without adequate family support.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-12-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 30133
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1116
NTR-old	NTR1151
CCMO	NL13205.078.06
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON30133

Resultaten

Samenvatting resultaten
Zielinski SM, Bouwmans CAM, Heetveld MJ, Bhandari M, Patka P, Van Lieshout EMM, on behalf of the FAITH trial investigators. The societal costs of femoral neck fracture patients treated with internal fixation. Osteoporos Int. 2014 Mar;25(3):875-885.

Zielinski SM, Viveiros H, Heetveld MJ, Swiontkowski MF, Bhandari M, Patka P, Van Lieshout EMM, on behalf of the FAITH trial investigators. Central coordination as an alternative for local coordination in a multicenter randomized controlled trial: the FAITH trial experience. Trials 2012;13(1):5.

Zielinski SM, Meeuwis MA, Heetveld MJ, Verhofstad MHJ, Roukema GR, Patka P, Van Lieshout EMM. Adherence to a femoral neck fracture treatment guideline. Int Orthop 2013 Jul;37(7):1327-1334

Zielinski SM, Keijsers NL, Praet NFE, Heetveld MJ, Bhandari M, Wilssens JP, Patka P, Van Lieshout EMM, on behalf of the FAITH trial investigators. Femoral Neck Shortening After Internal Fixation of a Femoral Neck Fracture. Orthopedics 2013 Jul 1;36(7):e849-e858.

Zielinski SM, Heetveld MJ, Bhandari M, Patka P, Van Lieshout EMM, FAITH trial investigators. Implant Removal After Internal Fixation of a Femoral Neck Fracture: Effects on Physical Functioning.
J Orthop Trauma 2015 Sep;29(9):e285-e292.