A Multi-Center Randomized Controlled Trial of Intramedullary Nails versus Sliding Hip Screws in the Management of Intertrochanteric Fractures of the Hip

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

Summary

ID

NL-OMON44033

Source
ToetsingOnline

Brief title
INSITE

Condition

- Fractures

Synonym
hip fracture, leg fracture, proximal femur fracture

Research involving
Human

Sponsors and support

Primary sponsor: Stryker

Source(s) of monetary or material Support: Stryker Trauma GmbH

Intervention

Keyword: Femoral Neck Fractures, Intertrochanteric Fracture, Intramedullary nail, Sliding hip screw

Outcome measures

Primary outcome

Health Related Quality of Life

To assess the impact of Gamma3 intramedullary nails versus sliding hip screws

on health-related quality of life as measured by the EuroQol-5D at 52 weeks

Secondary outcome

Health Related Quality of Life

health-related quality of life as measured with the Parker mobility score and

the Harris Hip Score.

Fracture healing rates

A fracture is to be considered healed when there is obliteration of the

fracture lines by newly formed bone along the cortices and within the

trabecular bone on anteroposterior and lateral (or oblique) radiographs.

Fracture-related adverse events

Including mortality, femoral shaft fracture, avascular necrosis (although rare in trochanteric fractures), nonunion, malunion (shortening, varus deformity, valgus deformity and rotational malunion), implant breakage or failure, and infection (i.e., superficial and deep).

Revision surgery rates

Study description

Background summary

the current literature provides conflicting evidence of which implant (the Gamma intramedullary nail versus the sliding hip screw) improves quality of life and has a lower revision surgery and complication rate. The small sample sizes, methodological limitations, and nonsignificant pooled estimate from the direct comparisons, leave the issue very much in doubt.

Study objective

The purpose of this study is to investigate whether Gamma3 intramedullary nails versus sliding hip screws will improve quality of life in patients with intertrochanteric fractures (hip fractures). We will also compare functional recovery, complications, fracture healing, and rates of revision surgeries between the two treatment groups.

Study design

a multi-center, concealed randomized controlled trial.

Intervention

Gamma3 Intramedullary Nails versus Sliding Hip Screws

Study burden and risks

Patients must fill in extra questionnaires at 4 moments. This will take maximum 60 minutes.

Moreover 1 extra clinical follow up is planned on 6 months (none X-ray).
Remaining follow up visit are according to standard care.
Beside this extra burden, there is no additional risk by participation in the trial (regular risks of operation)

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 18 years and older (with no upper age limit).
2. A trochanteric fracture (stable or unstable) confirmed with anteroposterior and lateral hip radiographs, computed tomography, or magnetic resonance imaging (MRI).
3. Low energy fracture (defined as a fall from standing height).
4. No other major trauma.
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 of the patient for operative fixation of the proximal femur.
7. Operative treatment within 7 days after the trauma*.
8. Provision of informed consent by patient or proxy.
*Operative treatment should take place as soon as possible as permitted by each institution*s standard of care.

Exclusion criteria

1. Associated major injuries of the lower extremity (i.e., ipsilateral and/or contralateral fractures of the foot, ankle, tibia, fibula, or knee; dislocations of the ankle, knee, or hip).
2. Retained hardware rond de aangedane proximale femur.
3. Infection around the proximal femur (i.e., soft tissue or bone).
4. Patients with disorders of bone metabolism other than osteoporosis (i.e., Paget*s disease, renal osteodystrophy, or osteomalacia).
5. Patients with Parkinson*s disease severe enough to increase the likelihood of falling or severe enough to compromise rehabilitation.
6. Patients with a subtrochanteric fracture.
7. Patients with a pathologic fracture.
8. Patients with a reverse oblique fracture pattern.
9. Obesity in the judgment of the attending surgeon.
10. Off-label use of the implant.
11. Patients with a previous history of frank dementia that would interfere with assessment of the primary outcome (i.e., EQ-5D at 1 year).
12. 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.
13. Patient is enrolled in another ongoing drug or surgical intervention trial.
14. If the attending surgeon believes that there is another reason to exclude this patient from INSITE. This reason will be documented on the case report forms.

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):	13-01-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-04-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01380444
CCMO	NL40846.100.12

Study results

Date completed:	27-01-2017
Actual enrolment:	21