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Intramedullary Nail versus Sliding hip screw Inter-Trochanteric Evaluation (INSITE)

Submission date
31/08/2011

Recruitment status
No longer recruiting

Registration date
18/10/2011

Overall study status
Completed

Last Edited
15/04/2019

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Intertrochanteric fractures are a common fracture of the hip. The hip joint connects the thighbone (femur) with the pelvis. Despite the name 'hip fracture', the break is actually below the hip joint, near the upper end of the thighbone. Following a fall, severe pain occurs in the area of the hip, groin and thigh. It is usually impossible to get up or walk. Very occasionally when the bone is cracked rather than completely broken, walking is possible although painful. Intertrochanteric fractures are commonly treated with internal fixation. With internal fixation, the fracture is repaired with metal screws or plates. The two common methods of internal fixation are Gamma intramedullary nails and sliding hip screws. It is unknown whether Gamma intramedullary nails have better results than sliding hip screws. 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.

Who can participate?
Our study will include 736 patients from medical centres located in Canada, the USA, Europe, and other international sites. We will enrol both male and female patients who are 18 years and older and who present an intertrochanteric fracture. Healthy volunteers will not be included

What does the study involve?
Patients will be assigned at random, that is, by a method of chance (like a flip of a coin), to one of two groups. There is a 1 in 2 chance (or a 50% chance) of being in the Gamma3 intramedullary nail group. There is a 1 in 2 chance (or a 50% chance) of being in the group that receives the sliding hip screw.

What are the possible benefits and risks of participating?
As with any surgical procedure of the lower extremity, potential risks include: femoral shaft (thigh bone) fractures, wound and deep infection, pulmonary embolism (a blood clot in the lung) /deep vein thrombosis (a blood clot in the leg), neurovascular injury (injury to nerves and blood vessels), compartment syndrome (increased pressure in muscles), nonunion (fracture does not heal), malunion (fracture heals incorrectly), and death. We cannot promise any personal benefits

to patients participating in this study. The results of this study may help other people with hip fractures in the future.

Where is the study run from?
Global Research Solutions (GRS) is based in Hamilton, ON, Canada. There will be up to 50 sites worldwide, with 20 sites across the USA and Canada, another 20 sites in Europe, and 10 sites in countries around the world.
In the UK the leading site will be Frenchay Hospital, Frenchay Park Road, Bristol BS16 1LE.

When is the study starting and how long is it expected to run for?
The study is expected to start in September 2011 and to end in September 2015.

Who is funding the study?
The study is funded by Stryker Osteosynthesis (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Dr Mohit Bhandari

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01380444

Secondary identifying numbers
14032012_INSITE_v2.0

Study information

Scientific Title
Intramedullary Nail versus Sliding hip screw Inter-Trochanteric Evaluation (INSITE): a multicenter randomized controlled trial

Acronym
INSITE

Study objectives
Among individuals 18 years and older with trochanteric fractures, what is the impact of Gamma3 Intramedullary Nails versus Sliding Hip Screws on health-related quality of life as measured by the EuroQol-5D?

On 05/01/2012 the following changes were made to the trial record:
1. The anticipated start date was changed from 01/09/2011 to 19/12/2011.
2. The anticipated end date was changed from 30/09/2015 to 31/12/2015.

On 07/05/2013 Spain and Sweden were removed from the countries of recruitment.

On 18/07/2014 the anticipated end date was changed from 31/12/2015 to 01/03/2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board Services, Canada, 17/08/2011

Study design
Definitive multicenter concealed randomized controlled trial

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
Trochanteric fracture

Interventions
Either Gamma3 intramedullary nail or Sliding/Dynamic Hip Screw [SHS / DHS] - depending on allocation by randomization system.

Patients allocated to the Gamma3 Intramedullary Nail treatment group will receive a Gamma3 intramedullary (Stryker) nail through a closed technique. Surgeons will follow the technique guides associated with the Gamma3 intramedullary nail manufacturer (Gamma3 Trochanteric Nail 180, B0300008, LOT G0710, Stryker 2010. and Gamma3 Trochanteric Long Nail, B0300009, LOT D3207, Stryker 2004). Augmentation of the implant fixation will be permitted and documented. Any type of navigation system and other add-on cleared products (CAS, Gamma 3 inside out) will be as well permitted and documented.

Patients allocated to the Sliding Hip Screw treatment group will receive a single larger diameter partially threaded screw affixed to the proximal femur with a side plate that has four holes and no supplemental fixations. Surgeons will be permitted to use any commercially available sliding hip screw implant (i.e., Stryker, DePuy, Synthes, Smith and Nephew, Zimmer, Hansson, etc.), and will insert implants as per the manufacturers technical guidelines. Kirschner wires should be used at the discretion of the operating surgeon. It is recommended that antirotational kirschner wires are used for lateral (basocervical) femoral head fractures. We recommend a center-to-center approach, while avoiding a superior and anterior approach. The use of a compression screw, manufacturer, reduction technique, the type of lag screw, if spiral blades and helical screws were used, and final screw position will be documented and based upon surgeon preference. The use of spiral blades and helical screws are protocol deviations, and justification for their use must be provided. Augmentation of the implant fixation will be permitted and documented.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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 in individuals with trochanteric fractures

Secondary outcome measures
1. Health-related quality of life at up to 104 weeks
2. To assess the impact of Gamma3 intramedullary nails versus sliding hip screws on health-related quality of life as measured with the Parker mobility score and the Harris Hip Score
3. Fracture healing rates at up to 104 weeks. 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
4. Fracture-related adverse events at up to 104 weeks, 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)
5. Revision surgery rates at up to 104 weeks. Any unplanned surgery after the initial fixation to promote fracture healing (nonunion), relieve pain (avascular necrosis, early or late implant failure), treat infection, or improve function will be considered a study event

Overall study start date
19/12/2011

Completion date
01/03/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/04/2012:
1. Adult men or women aged 18 years and older (with no upper age limit)
2. An intertrochanteric fracture (stable or unstable), AO Type 31-A1 or 31-A2, 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 (operative treatment should take place as soon as possible as permitted by each institution's standard of care)
8. Provision of informed consent by patient or proxy

Previous 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 (operative treatment should take place as soon as possible as permitted by each institution's standard of care)
8. Provision of informed consent by patient or proxy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
736 (368 in each treatment arm)

Key exclusion criteria

Current exclusion criteria as of 05/04/2012:
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 around the affected proximal 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, fracture AO Type 31-A3
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 Site 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

Previous 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 around the affected proximal femur
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4. Patients with disorders of bone metabolism other than osteoporosis (i.e. Paget's disease, renal osteodystrophy, or osteomalacia)
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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 followup. E.g. 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

Date of first enrolment
19/12/2011

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
Australia

Brazil

Canada

China

Colombia

Denmark

Germany

Netherlands

South Africa

United Kingdom

United States of America

Study participating centre
Global Research Solutions,
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Sponsor information

Organisation
Stryker Trauma GmbH (Germany)

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Sponsor type

Industry

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Funder(s)

Funder type
Research organisation

Funder Name
Global Research Solutions (Germany)

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