Effect of the lesser trochanter involvement in trochanteric hip fractures

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Primary Objective: To compare the function and strength of the hip of patients with a trochanteric fracture with and without a fracture of the lesser trochanter.Secondary Objective(s):The following parameters will be assessed and compared for...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON44135

Source
ToetsingOnline

Brief title
The Lesser Trochanter study.

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
hipfracture, trochanteric fracture

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: researchfonds MCH Bronovo

Intervention

Keyword: fracture, hip, Lesser trochanter

Outcome measures

Primary outcome

The main endpoint of the study is the function and strength of the hip 12 months after surgery measured with the HHS.

Secondary outcome

* Pain measured with a visual analogue scale on day 2 and at 6 weeks, 3 and 12 months after surgery.

* Migration of the lesser trochanter fragment on X-ray examinations in patients with trochanteric fractures with lesser trochanter involvement before surgery and at 6 weeks, 3 and 12 months after surgery.

* Quality of life measured with a quality of life questionnaire (EQ-5D) before surgery and at 6 weeks, 3 and 12 months after surgery.

* Duration of hospital stay (days).

* Duration of rehabilitation centre stay (days).

* Mental status measured with 6CIT-score before surgery and at 6 weeks and 12 months after surgery.

* Patient reported general mobility measured with the Katz before surgery and at 6 weeks, 3 and 12 months after surgery.

* The incidence and type of surgical related complications: deep and superficial wound infection, postoperative bleeding, 60-day and 1-year re-operation rate, and implant related failures (implant failure, implant dislocation, periprosthetic fracture).

* The incidence and type of non-surgical related complications: hospital,

60-day and 1-year mortality delirium, pneumonia, cardiac complications, urinary

tract infections, urinary retention, deep venous thrombosis, pulmonary

embolism, pressure sores, and rate of underfeeding on admission (Mini

Nutritional Assessment MNA).

Study description

Background summary

The incidence of proximal femoral fractures has steadily increased in the last few decades in accordance with the rise of the elderly population. Proximal femoral fractures can be categorized into femoral neck fractures and trochanteric fractures. The latter are classified as stable or unstable, depending on the integrity of the medial cortex. Although unstable trochanteric fractures often have a concomitant fracture of the lesser trochanter, little has been published about the dynamic and functional consequences of this specific involvement. The fragmented lesser trochanter, however, could play a major role in the rehabilitation process not only because the medial buttress is compromised, but also because it is the insertion point of the main flexor muscle and stabiliser of the hip: the iliopsoac muscle.

Study objective

Primary Objective:
To compare the function and strength of the hip of patients with a trochanteric fracture with and without a fracture of the lesser trochanter.

Secondary Objective(s):
The following parameters will be assessed and compared for patients with a trochanteric fracture with and without a fracture of the lesser trochanter:
* Patient reported pain in the hip region.
* Incidence and type of surgical complications.
* Incidence and type of non-surgical complications.
* Rehabilitation centre stay.
* Patient reported general mobility.
* Patient reported quality of life.
And:
* Migration of the lesser trochanter in patients with a trochanteric fracture

with a fracture of the lesser trochanter on X-ray examinations.

Study design

Single centre prospective observational patient-cohort study.

Study burden and risks

Participation in the study will not pose any additional risks for the patient. Patients will receive standard care and routine follow-up during a period of 12 months postoperatively, participants will be asked to come to the hospital for 2 additional visits. All measurements will be performed during these visits. The burden for the patients will include filling out a limited number of questionnaires and a few non-invasive measurements.

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

- Unilateral trochanteric fracture AO type 31 A1, A2 of A3.
- Age * 70 years.
- Fracture suitable for fixation with PFNa.

Exclusion criteria

- Other fractures restricting rehabilitation.
- High energy fracture of the hip.
- Malignant fractures.
- Previous fractures of the ipsi- or contralateral hip or femur.
- Non operative treated hip fractures.
- Injury Severity Score > 15.
- Patients incapable of physical therapy for rehabilitation by dementia
- Patients incapable of physical therapy for rehabilitation by physical restrictions.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-06-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL54746.098.16