Randomised controlled trial comparing the LFN (Lateral Femoral Nail) to the UFN (Unreamed Femoral Nail) in the treatment of femoral shaft fractures.

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1 Confirm comparable results in reduction and consolidation of the fracture fragments using the LFN vs the UFN2 Identifying a significant difference in the soft tissue damage between the LFN and the UFN

Ethical review	Approved WMO
Status	Will not start
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON32898

Source
ToetsingOnline

Brief title
RCT LFN vs UFN

Condition

- Procedural related injuries and complications NEC
- Fractures

Synonym
thigh fracture, upper leg fracture

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: femoral shaft fracture, intramedullary nail, soft tissue damage, Superior gluteal nerve

Outcome measures

Primary outcome

Damage to the superior gluteal nerve (measured by EMG)

Abduction force (measured by Biodex)

Functional combined score (Oxford hip score, Oxford knee score and the

Fulkeson-Shea score)

Secondary outcome

Deformities of the fracture

Consolidation of the fracture

VAS pain score

Range of motion

Study description

Background summary

The LFN (lateral femoral nail) is a new, helical shaped implant used for the treatment of femoral shaft fractures. The point of entry of the LFN is located lateral to the tip of the greater trochanter. In comparison to the conventional reamed/unreamed straight femoral nail, that has its entry point in the piriformic fossa, the entry point of the LFN can be more easily located and it is expected this new implant will lead to less soft tissue damage.

Study objective

1 Confirm comparable results in reduction and consolidation of the fracture fragments using the LFN vs the UFN

2 Identifying a significant difference in the soft tissue damage between the LFN and the UFN

Study design

Prospective randomised controlled trial
Inclusion of patients will be performed at the moment there is an indication for an intramedullary femoral nail.
Patients will be randomised into two groups.
50 patients will undergo surgery receiving the LFN, 50 patients will be treated with the UFN.
There will be a follow-up period of 1 year with visits at 6 weeks, 3 months, 6 months and 1 year. These visits will all fall within the standard follow-up after this kind of fracture.

Extra investigations necessary for this research:
-Clinical CT scan for measuring rotational deformities
-Abduction force measurements performed by the fysiotherapist using Biodex (4 times)
-Needle EMG after 6 weeks measuring function of the superior gluteal nerve. The EMG will be repeated after 1 year if the first measurement is abnormal
-Filling out a questionnaire during the outclinic visits at 6 weeks, 3 months, 6 months and 1 year

Intervention

Implantation of the LFN (lateral femoral nail)

Study burden and risks

The EMG is the main extra burden for the patients because it is an uncomfortable investigation performed with a needle. However this investigation is essential for this research to be able come to an signifcant conclusion.

The risk associated with participation is only small. The helical shape of the new implant could cause rotational deformity of the fracture and iatrogenic fractures. At this moment a prospective multicentre case-series study is being performed on the LFN. 182 patients are included so far with untill now 6 iatrogenic fractuers and 2 malrotations (www.aofoundation.org)

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

Femoral shaft fracture (AO type 32) with the indication for an intramedullary nail

Exclusion criteria

life expectancy <1 year
Soft tissue damage to such extent that comparison between the groups will be impossible
Limping before the fracture caused by preexistent damage
Bilateral fracture

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	unreamed femoral nail and expert lateral femoral nail
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-10-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL24529.008.08