Intramedullary Nailing of proximal femur fractures: Gamma 3 Nail versus Fixion Proximal Femur Nailing System

Published: 06-11-2008
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The objective is to investigate the excess value of the Fixion Proximal Femur Nailing System in comparison with the Gamma 3 Nail in patients with an unstable pertrochanteric femur fracture.

Ethical review	Approved WMO
Status	Completed
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON31672

Source
ToetsingOnline

Brief title
Gammafix

Condition

- Fractures

Synonym
hip fracture, proximal femur fracture

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Atrium Medisch Centrum

Intervention

Keyword: expandalble, femur, fixion, intramedullary

Outcome measures

Primary outcome

The primary objective of the study is to investigate the number of

complications.

Secondary outcome

secondary objectives will be procedure time, peroperative fluoroscopic time,

number of infections, hospitalisation time and resumption of full activities.

Study description

Background summary

The Fixion TM PF Nailing System is a relatively new intramedullary nail, that is not investigated much. This nail is expandable and self-locking, so the inital diameter to introduce the nail is smal. No interlocking screws are needed. At the Atrium Medical centre unstable pertrochanteric femur fractures are treated with the Gamma 3 Nail. We want to use the FixionTM PF Nailing System in pertrochanteric femur fractures. The hypothesis is that there is a reduced infection risk, a minimized fluoroscopy exposure and a reduced procedure time, in comparison with the Gamma 3 Nail.

Study objective

The objective is to investigate the excess value of the Fixion Proximal Femur Nailing System in comparison with the Gamma 3 Nail in patients with an unstable pertrochanteric femur fracture.

Study design

The study is a single centre, prospective, randomized trial

Intervention

Gamma 3 Nail versus Fixion Proximal Femur Nailing System

Study burden and risks

The risks associated with participation are no different from the regular therapy and follow-up of an unstable pertrochanteric femur fracture.

Contacts

Public
Atrium Medisch Centrum

postbus 4446
6401 CX Heerlen
Nederland
Scientific
Atrium Medisch Centrum

postbus 4446
6401 CX Heerlen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

proximal femur fractures with AO-classification 31 A1.1 - A3.3;> 18 years;admitted to hospital

Exclusion criteria

primairy bone disease
- fibrous dysplasia
- Gaucher's disease
- osteogenesis imperfecta
- osteomalcia
- osteomyelitis
- Pagets disease
- renal oseodystrophy;life expectency < 1 year;patient can't speak Dutch

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:	Completed
Start date (anticipated):	01-11-2009
Enrollment:	244
Type:	Actual

Ethics review

Approved WMO

Date:	06-11-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL20680.096.07