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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24171

Source
Nationaal Trial Register

Brief title
Gammafix

Health condition

Fixion Nail in proximal femur fractures
(NLD: Fixion nail in proximale femur fracturen).

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Major and minor implant related;

2. complication rate;

Secondary outcome

1. Procedure time;

2. preoperative fluoroscopic rime;

3. number of infections;

4. resumption of full activities;

5. mortality.

Study description

Background summary

The Fixion Proximal Femur Nailing System
is a relatively new intramedullar nail. The background of the study is to investigate it's use in (un)stable proximal femur fractures. The hypothesis is that there is a reduced infection risk, a minimized fluoroscopy exposure, reduced mortality and a reduced procedure time, in comparison with the Gamma 3 Nail.
It's a single blinded randomized clinical evaluation of the treatment and results of intramedullary nailing for (un)stable proximal femur fractures. Patients will be randomized for the Gamma 3 nail group or the Fixion PF Nailing System.

The study population will be human volunteers with a minimal age of 18 years old with a (un)stable proximal femur fracture.

The risks associated with participation are not different from the regular therapy and follow-up of a pertrochanteric femur fracture.

Study objective

Treatment with Fixion Proximal Femur Nailing System will give less complications than treatment with Gamma 3 Nail in unstable proximal femur fractures.

Study design

0, 3, 6, 12, 24, 48 weeks postoperative

Intervention

Intervention: Fixion Proximal Femur Nailing System.

Control: Gamma 3 nail.

Contacts

Public
Postbus 4446

A.M. Bek
Heerlen 6401 CX
The Netherlands
045-5766666
Scientific
Postbus 4446

A.M. Bek
Heerlen 6401 CX
The Netherlands
045-5766666

Eligibility criteria

Inclusion criteria

1. Proximal femur fractures with AO-classification 31 A1.1 - A3.3;

2. >18 years;

3. admitted to hospital.

Exclusion criteria

1. Primairy bone disease:

a. fibrous dysplasia;

b. Gaucher's disease;

c. osteogenesis imperfecta;

d. osteomalcia;

e. osteomyelitis;

f. Pagets disease;

g. renal oseodystrophy;

h. periprothetic fractures;

2. life expectency <1 year;

3. 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	244
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1098
NTR-old	NTR1133
Other	METC Atrium-Maasland : nog niet bekend, wordt 30 november ingediend
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A