

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

NTR

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 time;
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 its 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

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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. Primary 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 expectancy <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