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 titleGammafix

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 followup 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

2 - Intramedullary Nailing of proximal femur fractures: Gamma 3 Nail versus Fixion P ... 25-05-2025

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;
 - 3 Intramedullary Nailing of proximal femur fractures: Gamma 3 Nail versus Fixion P ... 25-05-2025

- 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 Wordt niet meer aangevraagd

Study results

Summary results

N/A