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

Published: 06-11-2008 Last updated: 30-11-2024

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

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# **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

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# **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
Туре:	Actual

# **Ethics review**

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

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# **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** CCMO ID NL20680.096.07