# Intramedullary Nailing of Diaphyseal Humeral Fractures - T2\* Humeral Nail versus Fixion ® Intramedullary Humeral Nail

Published: 26-06-2007 Last updated: 08-05-2024

The primary objective of the study is to investigate the number of complications (infection, nonunion, nerve damage). Secondary objectives will be procedure time, peroperative fluoroscopic , hospitalisation time and resumption of full activities.

| Ethical review        | Approved WMO   |
|-----------------------|----------------|
| Status                | Will not start |
| Health condition type | Fractures      |
| Study type            | Interventional |

# Summary

# ID

NL-OMON31223

**Source** ToetsingOnline

**Brief title** H-FINSS

# Condition

• Fractures

Synonym Diaphyseal Humerus Fracture (Humerus Shaft Fracture)

#### **Research involving**

Human

### **Sponsors and support**

#### Primary sponsor: Atrium Medisch Centrum

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#### Source(s) of monetary or material Support: door ziekenhuis zelf

### Intervention

Keyword: Fixion, Humerus, Intramedullary, Nailing

### **Outcome measures**

#### **Primary outcome**

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

complications (infection, nonunion, nerve damage).

#### Secondary outcome

Secondary objectives will be procedure time, peroperative fluoroscopic,

hospitalisation time and resumption of full activities.

# **Study description**

#### **Background summary**

The Fixion® IM Humeral nail is a relatively new intramedullary nail, that isn\*t much investigated. The background of the study is to investigate it\*s use in fractures of the humeral shaft. The hypothesis is that there is a reduced infection risk, a minimized fluoroscopy exposure and a reduced procedure time, in comparison with the T2\* Humeral nail.

#### **Study objective**

The primary objective of the study is to investigate the number of complications (infection, nonunion, nerve damage). Secondary objectives will be procedure time, peroperative fluoroscopic, hospitalisation time and resumption of full activities.

#### Study design

The study is a multicenter prospective single blinded randomized clinical evaluation of the treatment and results of intramedullary nailing for humeral shaft fractures. Patients will be randomized for the T2\* Humeral nail group or the Fixion ® IM Humeral nail group

#### Intervention

T2\* Humeral nail or the Fixion ® IM Humeral nail

#### Study burden and risks

The risks associated with participation are no different from the regular therapy and follow-up of a humeral shaft fracture.

# Contacts

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

### **Inclusion criteria**

minimal age of 18 years or older with a humerus diaphyseal fracture

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# **Exclusion criteria**

- Gustilo and Anderson classification III-C
- Primary bone disease
- Postoperative treatment in an hospital not participating in the study

# Study design

# Design

| Study type:         | Interventional                |
|---------------------|-------------------------------|
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |
| Control:            | Active                        |
| Primary purpose:    | Treatment                     |

### Recruitment

КП

| INL                       |                |
|---------------------------|----------------|
| Recruitment status:       | Will not start |
| Start date (anticipated): | 01-05-2007     |
| Enrollment:               | 120            |
| Туре:                     | Anticipated    |

# **Ethics review**

| Approved WMO       |                                   |
|--------------------|-----------------------------------|
| Date:              | 26-06-2007                        |
| 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 CCMO ID NL17500.096.07