Intramedullary Nailing of Diaphyseal Humeral Fractures - T2™ Humeral Nail versus Fixion ® Intramedullary Humeral Nail

No registrations found.

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

Summary

ID

NL-OMON20978

Source
Nationaal Trial Register

Brief title
H-FINSS (Humeral - Fixion Intramedullary Nailing System Study)

Health condition

Intramedullary - Nailing - Diaphyseal - Humeral Fractures - Fixion Nail - T2 Nail - Intramedullair - humerusschacht - fractuur

Sponsors and support

Source(s) of monetary or material Support: self-financing research

Intervention

Outcome measures

Primary outcome

The primary objective of the study is to investigate the peroperative fluoroscopic time.

Secondary outcome

Secondary objectives will be:
1. procedure time;
2. number of infections;
3. number of complications;
4. hospitalisation time;
5. resumption of full activities.

Study description

Background summary

Rationale: 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.

Objective: The primary objective of the study is to investigate the peroperative fluoroscopic time. Secondary objectives will be procedure time, number of infections, number of complications, 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.

Study population: The study population will be human volunteers with a minimal age of 18 years old with a humeral shaft fracture.

Intervention: T2™ Humeral nail or the Fixion ® IM Humeral nail

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks associated with participation are no different from the regular therapy and follow-up of a humeral shaft fracture.

Study objective

Theoretically there are many advantages of using the Fixion ® IM Humeral nail, like a significant reduced surgical and fluoroscopic exposure time. The procedure is simple and minimal invasive. No interlocking screws are needed, thus there is a reduced risk of infection. Reaming becomes an optional procedure. Due to the abutment of the longitudinal bars along the entire length of the medullary canal walls, high resistance to the rotational forces is

achieved. Removal will be easier as the nail is deflatable. The Fixion® Intramedullary Nail combines the advantages of unreamed nailing with regards to preservation of endosteal blood supply and the biomechanical advantages of reamed nailing due to the bone-nail contact. Postoperative the arm is direct stable for practice and after 6 weeks stable for daily usage.

Intervention

The patient with the suspicion of a humeral shaft fracture will be examined at the first aid department and will be diagnosed with x-ray. In case of open fractures the wound will be brief inspected, applicated with a sterile dressings and administration of intravenous antibiotics. After the diagnose of a humeral shaft fracture the first aid doctor will check if the patient meets the inclusion- and exclusion criteria, if that's the cases, the patient will be informed about the study and will be asked to give informed consent. After informed consent is given the patient will be randomized in one of the two groups.
In the operating room a thorough wound debridement will be performed with excision of all devitalised soft tissue prior to nailing. Primary wound closure should normally not be performed. Small wounds will close by secondary intention and larger wounds should be covered by either split thickness skin grafts or, in case of bone exposure, a fasciocutaneous or a free vascular flap.
Implantation of intramedullary nails will be performed following the recommendations given in the instructional manuals of Stryker and Disc-O-Tech, and with the original materials provided by these companies. Proximal or distal locking has to be performed with one locking screws, depending on a retro- or antegrade insertion. Both intramedullary nailing devices are suitable for static fixation. Static fixation will be performed in complex and/or length unstable fractures. In case of any doubt on the stability of osteosynthesis, static fixation is recommended.
To assess adequate timing, the moment of skin incision, closure, and reduction time must be reported. Peri-operatively, fluoroscopy time will be recorded.

Quality of reduction is determined at the first postoperative X-ray; angulation (anterior/posterior or varus/valgus) and shortening (or lengthening) will be measured. Rotation will be measured by physical examination.

Contacts

Public
Atrium MC/ Afdeling Chirurgie
Postbus 4446
M.W. Gosler
Henri Dunantstraat 5
Heerlen 6401 CX
The Netherlands
+31 45-5766599

Scientific
Atrium MC/ Afdeling Chirurgie
Postbus 4446
M.W. Gosler
Henri Dunantstraat 5
Heerlen 6401 CX
The Netherlands
+31 45-5766599

Eligibility criteria

Inclusion criteria

Human volunteers with a minimal age of 18 years old with a humeral shaft fracture.

Exclusion criteria

1. Gustilo and Anderson classification III-C;
2. Primary bone disease:
a. Fibrous Dysplasia;
b. Gaucher's Disease;
c. Osteogenesis Imperfecta;
d. Osteomalacia;
e. Osteomyelitis;
f. Pagets Disease;
g. Renal Osteodystrophy;
3. Postoperative treatment in an hospital not participating in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	120
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	NL923
NTR-old	NTR947
Other	:
ISRCTN	ISRCTN00265392

Study results