

Intramedullary nailing of diaphyseal humeral fractures: T2™ humeral nail versus Fixion® intramedullary humeral nail

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/09/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr M.W. Gosler

Contact details

Atrium Medisch Centrum
Department of Surgery/Afdeling Chirurgie
P.O. Box 4446
Heerlen
Netherlands
6401 CX
+31 (0)45 5766599
FixionNailStudy@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Intramedullary nailing of diaphyseal humeral fractures: T2™ humeral nail versus Fixion® intramedullary humeral nail

Acronym

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

Study objectives

Theoretically there are many advantages of using the Fixion® Intramedullary (IM) humeral nail, like a significant reduced surgical and fluoroscopic exposure time. The procedure is simple and minimally 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. Postoperatively the arm is stable for practice and after six weeks stable for daily usage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending from the local ethics committee (Medisch Ethische Toetsingscommissie AtriumMC - Maaslandziekenhuis) as of 30/05/2007.

Study design

Randomised, single blinded, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Humeral Fractures and Fixion® Intramedullary (IM) humeral nail

Interventions

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 briefly inspected, sterile dressings will be applied and intravenous antibiotics administered. After the diagnosis of a humeral shaft fracture the first aid doctor will check if the patient meets the inclusion and exclusion criteria, if that's the case, 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 randomised 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 screw, 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Patients in the study will be assessed in the early postoperative period prior to discharge, at the trauma clinic at 3, 6, 12, 18, 24, 36 and 48 weeks post-trauma and in case of complications at least every four weeks. To achieve an adequate estimation on consolidation time, it is important to make check X-rays at every visit, until consolidation is achieved.

Secondary outcome measures

Secondary objectives will be:

1. Procedure time
2. Number of infections
3. Number of complications
4. Hospitalisation time
5. Resumption of full activities

Patients in the study will be assessed in the early postoperative period prior to discharge, at the trauma clinic at 3, 6, 12, 18, 24, 36 and 48 weeks post-trauma and in case of complications at

least every four weeks. To achieve an adequate estimation on consolidation time, it is important to make check X-rays at every visit, until consolidation is achieved.

Overall study start date

01/05/2007

Completion date

01/05/2009

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

120

Key exclusion criteria

1. Gustilo and Anderson classification IIIC
2. Primary bone disease:
 - 2.1. Fibrous dysplasia
 - 2.2. Gaucher's disease
 - 2.3. Osteogenesis imperfecta
 - 2.4. Osteomalacia
 - 2.5. Osteomyelitis
 - 2.6. Pagets disease
 - 2.7. Renal osteodystrophy
3. Postoperative treatment in an hospital not participating in the study

Date of first enrolment

01/05/2007

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Atrium Medisch Centrum

Heerlen

Netherlands

6401 CX

Sponsor information

Organisation

Atrium Medical Centre (Atrium Medisch Centrum) (The Netherlands)

Sponsor details

P.O. Box 4446

Heerlen

Netherlands

6401 CX

Sponsor type

Hospital/treatment centre

Website

<http://www.atriummc.nl/>

ROR

<https://ror.org/0367sy10>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Atrium Medical Centre (Atrium Medisch Centrum) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration