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

Submission date 30/05/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/05/2007	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL923 (NTR947)

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
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6401 CX

Sponsor information

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

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Sponsor type
Hospital/treatment centre

Website
http://www.atriummc.nl/

ROR
https://ror.org/0367sye10

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