



PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Long-term clinical-radiographic results after angle-stable plate osteosynthesis of proximal humeral fractures

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

The aim was to assess mid-term outcomes in elderly patients (>70 years) with proximal humeral fractures treated with angular stable plate fixation and compare the test-retest agreement of the telephone-based score assessments.

Patients with bony consolidated proximal humeral fractures were interviewed using different scores. In addition, the same survey was repeated by another investigator to assess the consistency of the results survey

Organizational Data

- DRKS-ID: **DRKS00017489**
- Date of Registration in DRKS: **2019/06/17**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **250/2011BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**

Secondary IDs



Health condition or Problem studied

- ICD10: **S42.2 - Fracture of upper end of humerus**

Interventions/Observational Groups

- Arm 1: **Outcome evaluation using functional scores / questionnaires (Constant Score, DASH Score, Oxford Shoulder Score)**
After osseous consolidation of the fracture, study participants were contacted by telephone and the above mentioned scores were taken to assess the functional outcome.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

The aim of the study is to evaluate the functional outcome after surgically treated proximal humeral fracture. The Constant Score, DASH Score and Oxford Shoulder Score were used for the evaluation. These scores were assessed after bony consolidation.

Secondary Outcome

Test-Retest agreement

Countries of recruitment

- **DE Germany**



Locations of Recruitment

- University Medical Center **Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/06**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **70 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Proximal humeral fracture, ORIF

Exclusion criteria

age < 70 years, infection, re-fracture

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries



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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2015/08/11**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.