

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Functional Outcome of therapy of elbow dislocation - medium- and long-term results of conservative and surgical therapy of elbow dislocations with or without related fractures

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

Retrospective study registering the clinical and functional outcome of elbow dislocation of patients who are of age and were treated conservatively or surgically in the space of time from January 2010 to December 2013 at the BGU Tübingen. Therefore a questionnaire with questions about the elbow's movement, strength and stability in everyday life, when doing sports and when working as well as the current pain. The elbow's functionality is going to be evaluated by several scores with the view to find out, which treatment has got die best long-term results.

Hypothesis: Is the surgical therapy superior in the long term to the conservative reduction?

Organizational Data

- DRKS-ID: **DRKS00009911**
- Date of Registration in DRKS: **2016/01/28**
- 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.: **719/2015BO2 , Ethik-Kommission an der Medizinischen Fakultät der Eberhard-Karls-Universität und am Universitätsklinikum Tübingen**



Secondary IDs

Health condition or Problem studied

- ICD10: **S53 - Dislocation, sprain and strain of joints and ligaments of elbow**

Interventions/Observational Groups

- Arm 1: **conservative therapy: closed reduction (splint or dynamic splint for at least two weeks)**
Questionnaire asking them to agility, strength and stability of the elbow in everyday life, in Sport and at work, as well as the acute pain and the functionality of the elbow . Assessment using various scores.
- Arm 2: **surgical therapy: open reduction (screws, pins)**
Questionnaire asking them to agility, strength and stability of the elbow in everyday life, in Sport and at work, as well as the acute pain and the functionality of the elbow . Assessment using various scores.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Elbow function (movement, strength, pain, stability) and consequences on quality of Life by questionnaire and examination according to the following scores: VAS, DASH, Score of Broberg and Morrey, MEPI, EuroQol-5D
The Primary Outcome is set on a date when the therapy is at least finished for one year.



Secondary Outcome

long-term outcome and complications (questionnaire)

The Secondary Outcome is evaluated five years after having finished the treatment.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Berufsgenossenschaftliche Unfallklinik, Tübingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/02**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

conservative or surgical therapy of elbow dislocation in the space of time from January 2010 to December 2012

Exclusion criteria

**Patient refuses to take part at the study.
It's not possible for the patient to appear to the follow-up examination and to be interviewed.**

Addresses



■ **Primary Sponsor**

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72076 Tübingen
Germany

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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)**

Berufsgenossenschaftliche Unfallklinik Tübingen
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**Deutsches Register
Klinischer Studien**

**German Clinical
Trials Register**

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

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E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* 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.