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

Trial Description

Title

Long-term results after non-operative and operative treatment of radial neck fractures in adults

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The isolated fracture of the radial neck is a rare injury in adults. Most of the available studies regarding the outcome of these fractures have combined results of radial neck and head fractures. Few studies have examined the results of isolated fractures. In our study we evaluate the clinical and radiological outcome of radial neck fractures following non-operative and operative treatment.

Brief Summary in Scientific Language

Fractures of the proximal radius can affect the radial head as well as the radial neck. While in children radial neck fractures are common, this is a rare entity in adults. Nonetheless, these fractures can cause severe impairments of the function of the elbow regarding range of motion and pain. In this study, several clinical outcome scores as well as radiological parameters are evaluated to compare operative vs. non-operative treatment in relation to the initial radiologic findings.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012836**
- Date of Registration in DRKS: **2017/08/07**

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Date of Registration in DRKS: **2017/08/07**

- 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.: **837.261.15 (10029) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **S52.12 - [generalization S52.1: Fracture of upper end of radius]**

Interventions/Observational Groups

- Arm 1: **Operatively treated patients - parameters consist of radiological results based on the quality of reduction postoperatively and clinical results based on the follow up examination (see above for scores), at least 2 years after the injury**
- Arm 2: **Non-operatively treated patients - parameters consist of radiological results based on the changes in fracture dislocation in follow-up x-rays and clinical results based on the follow-up examination (see above for scores), at least 2 years after the injury**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Other**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Clinical results: Scores MEPS (Mayo Elbow Performance Score) and DASH (Disabilities of the Arm, Shoulder and Hand) at the follow-up examination (at least 2 years after the injury)

Secondary Outcome

Radiological results: fracture dislocation in follow-up films

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **BG Klinik Ludwigshafen, Ludwigshafen am Rhein**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/01**
- Target Sample Size: **34**
- 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

- fracture of the radial head without other relevant injuries of the elbow that were treated between September 2000 and August 2013
- minimal follow-up of two years
- minimum age 18 years

Exclusion criteria

- illnesses with impairment of bone quality or joint movement
- refused or not able to take part in the study

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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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/04/01**

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.*