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

Trial Description

Title

Two-stage Revision shoulder arthroplasty after deep infection of the shoulder: functional outcome, complications ans prognoses

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

The incidence of infections after primary shoulder arthroplasty is between 1 – 5% in literature, with even higher rates after reverse shoulder arthroplasty. The shoulder infection can be treated by surgical debridement with one stage or two stage exchange of the prosthesis or resection arthroplasty. The best outcomes for eradication of the infection has been reported by one or two stage revision and the resection arthroplasty. In this study we follow patients with deep infections of the shoulder after arthroplasties, rotator cuff surgery or fracture fixation that were treated with two stage revision arthroplasty. The patients have to be over 18 years old. One year after arthroplasty we check the functional outcome, complications like reinfection or dislocation and the general satisfaction of the patients.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016927**
- Date of Registration in DRKS: **2019/03/19**

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Date of Registration in DRKS: **2019/03/19**

- 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.: **2018-13493 , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- ICD10: **T84.5 - Infection and inflammatory reaction due to internal joint prosthesis**
- ICD10: **T84.6 - Infection and inflammatory reaction due to internal fixation device [any site]**
- ICD10: **M00.91 - [generalization M00.9: Pyogenic arthritis, unspecified]**

Interventions/Observational Groups

- Arm 1: **Patients, aged 18 or older, which had a deep infection of the shoulder and a two stage Revision shoulder arthroplasty**

  Follow-up one year after arthroplasty: clinical examination, anaysis of questionnaires and the patients health record

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

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): **N/A**

Primary Outcome

- DASH (Disabilities of the arm, the shoulder and the Hand) score one year after arthroplasty
- Constant Shoulder Score one year after arthroplasty

Secondary Outcome

- Satisfaction of the patients one year after arthroplasty, acquisition by standardised questionnaire
- Reinfection- and dislocationrate one year after arthroplasty, acquisition by anamnesis and the patients health record

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: **2019/01/01**
- Target Sample Size: **20**
- 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

- Patients aged older than 18
- Deep infection of the shoulder after surgery
- two-stage revision shoulderarthroplasty

Exclusion criteria

Patients younger than 18 years.

Addresses

- **Primary Sponsor**

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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 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.*