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

Trial Description

Title

case-control study on how the type and duration of antimicrobial treatment effects the probability of recurring infections endoprothesis or fracture fixation devices

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

There are no standardized recommendations for antimicrobial treatment after infections of fracture fixation device. Doctors recommend an antimicrobial treatment varying from some days to more than 6 weeks. Some experts prefer even a longer treatment. They also depend on the type of indwelling implant (e.g., arthroplasty versus osteosynthesis plate), patient's risk profile, surgical strategy, and microbial spectrum. There is evidence from observational studies that prolonged application of antibiotics does not increase the probability of cure, and that antibiotic treatment exceeding six weeks may even lead to worse outcomes.
The aim of this study is to determine the influence of the duration and the kind of antimicrobial treatment after surgical treatment of infections of fracture fixation devices or hip- and knee arthroplasty for the probability of a recurring infection in an one-year-follow-up. Endpoint of this study is the infection free implant survival one year after the last surgical debridement.
Endpoint of this study is the infection free implant survival one year after the last surgical debridement.
The study is a retrospective case-control-study. Routine data records from the study centers will be analyzed.
Study participants will be divided into two groups depending on the course of infection. Cases will be patients with a failed therapy which means patients with a recurring infection one year after the last surgical debridment. Controls are defined as patients with a successful first treatment of the infection. For these patients, no recurring infection in a one-year-follow-up is noticed.

Brief Summary in Scientific Language

The appropriate duration of antimicrobial treatment after radical debridement of infected surgical hardware is an unsolved problem. Recommendations vary from country to country and even from institution to institution, ranging from two weeks to six months and longer. They also depend on the type of indwelling implant (e.g., arthroplasty versus osteosynthesis plate), patient's risk profile,

surgical strategy, and microbial spectrum. There is evidence from observational studies that prolonged application of antibiotics does not increase the probability of cure, and that antibiotic treatment exceeding six weeks may even lead to worse outcomes. The aim of the study is to investigate the impact factors of antimicrobial treatment for the probability of a rrecurring infection after infections of fracture fixation devices.

Organizational Data

- DRKS-ID: **DRKS00005283**
- Date of Registration in DRKS: **2013/09/03**
- 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.: **BB026/13 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

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: **T84.7 - Infection and inflammatory reaction due to other internal orthopaedic prosthetic devices, implants and grafts**

Interventions/Observational Groups

- Arm 1: **Cases will be patients with a failed therapy which means patients with a recurring infection one year after the last surgical debridement. Routine data records from the study centers will be retrospectively analyzed.**
- Arm 2: **Controls are defined as patients with a successful first treatment of the infection. For these patients, no recurring infection in a one-year-follow-up is noticed. Routine data records from the study centers will be retrospectively analyzed.**

Characteristics

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

Study Type: **Non-interventional**

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

- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Duration of the systemic antimicrobial treatment after the last surgical intervention.

Secondary Outcome

Kind of systemic antimicrobial therapy (monotherapy or combined treatment, dose, application, substances)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abteilung für Unfall- und Wierderherstellungschirurgie, Greifswald**
- University Medical Center **Klinik und Poliklinik für Orthopädie, Rostock**
- Medical Center **Unfallkrankenhaus Berlin, Klinik für Unfallchirurgie und Orthopädie, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/03/15**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2013/03/15**

Target Sample Size: **1000**

Monocenter/Multicenter trial: **Multicenter trial**

- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Infected fracture fixation device (i.e., plate-screw-combination) of a long bone (i.e., humerus, forearm, femur, tibia, or fibula), of the ankle joint (inside and outside ankle), of the heel bone proven by CDC criteria and / or tissue samples and / or surgical findings OR
Infected total knee or hip arthroplasty proven by CDC criteria and / or tissue samples and / or surgical findings

Exclusion criteria

none

Addresses

- **Primary Sponsor**

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Fleischmannstraße 8
17475 Greifswald
Germany

Telephone: **[---]***
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E-mail: **[---]***
URL: **www.klinikum.uni-greifswald.de**

- **Contact for Scientific Queries**

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Mr. Priv.-Doz. Dr. med., MSc (Epi) Dirk Stengel
Warener Str. 7

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Friedrichstraße 130 B
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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

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

Universitätsklinikum Greifswald
Fleischmannstraße 8
17475 Greifswald
Germany

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

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E-mail: **[---]***
URL: **www.klinikum.uni-greifswald.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/12/31**

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.*