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

Trial Description

Title

Intramedullary nailing with temporary ankle and subtalar arthrodesis versus external fixation in patients with infected non-unions of the distal tibia – a comparative retrospective analysis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Background
The successful treatment of infected non-unions of the distal tibia remains challenging. The aim of therapy is a permanent control of infection as well as a weight carrying capacity of the extremity.
Multiple operative approaches and techniques are described for aseptic non-unions of the distal tibia in the current literature. The arthrodesis of the ankle is presumed to be a salvage procedure in the case of severely comminuted tibial pilon fractures. A retrograde intramedullary nail is frequently used in these cases. An arthrodesis of the ankle without removing the cartilage is described in elderly patients with considerable comorbidities and distal tibial fractures without pilon fracture.
The treatment of infected non-unions of the distal tibia is more complex. There is established consensus, that internal fixation should be avoided in the case of chronic osteomyelitis. Especially intramedullary implants are rarely used in patients with chronic osteomyelitis because of the risk of an intramedullary phlegmon in the case of a recurrence of infection. Therefore, infected non-unions are frequently treated with external fixation. This requires a high compliance of the patient. Furthermore, it can be difficult to achieve adequate stability.
We use retrograde intramedullary nails for temporary arthrodesis of the ankle in patients with infected non-unions of the distal tibia, even if the ankle is not affected. The cartilage of the ankle and the subtalar joint is not removed. After bony fusion of the fracture, the intramedullary nail is removed. A high primary stability is advantageous. On the other hand, the arthrodesis of the ankle and the subtalar joint is disadvantageous as well as the intramedullary position of the implant.
To our knowledge, the above-mentioned treatment method is not described for this indication in current literature.
In our retrospective study, we compare the outcome of patients with infected non-unions of the distal tibia, who were treated either with retrograde intramedullary nail or with external fixator (golden standard).

Material and method

Patients collective
Patients with an infected non-union of the distal tibia, who were treated with either retrograde intramedullary nail or external fixator between 06/15 and 02/19, are analyzed.
Inclusion criteria are age > 18 years. Exclusion criteria are patients with an ankle empyema or other operative technique.
Epidemiologic data, pre-, peri- and postoperative course will be analyzed. Follow-up will be analyzed until 12/19.
The primary endpoint is bony fusion of the infected non-union. Secondary endpoints are successful control of infection during follow-up, full weight bearing and the range of motion of the ankle after removal of the intramedullary nail. All kinds of complications will be evaluated.

Brief Summary in Scientific Language

Background
The successful treatment of infected non-unions of the distal tibia remains challenging. The aim of therapy is a permanent control of infection as well as a weight carrying capacity of the extremity.
Multiple operative approaches and techniques are described for aseptic non-unions of the distal tibia in the current literature. The arthrodesis of the ankle is presumed to be a salvage procedure in the case of severely comminuted tibial pilon fractures. A retrograde intramedullary nail is frequently used in these cases. An arthrodesis of the ankle without removing the cartilage is described in elderly patients with considerable comorbidities and distal tibial fractures without pilon fracture.
The treatment of infected non-unions of the distal tibia is more complex. There is established consensus, that internal fixation should be avoided in the case of chronic osteomyelitis. Especially intramedullary implants are rarely used in patients with chronic osteomyelitis because of the risk of an intramedullary phlegmon in the case of a recurrence of infection. Therefore, infected non-unions are frequently treated with external fixation. This means low comfort, the risk of pin-infection and/ or loosening of the pins, partial weight bearing and therefore requires a high compliance of the patient. The ankle has to be bridged with the external fixator in the case of distal tibial fractures. It can be difficult to achieve an adequate stability because of small distal fragments.
We use retrograde intramedullary nails for temporary arthrodesis of the ankle in patients with infected non-unions of the distal tibia, even if the ankle is not affected. The cartilage of the ankle and the subtalar joint is not removed. After bony fusion of the fracture, the intramedullary nail is removed. A high primary stability is advantageous as well as the protection of the soft tissues during implantation. On the other hand, the – temporary – arthrodesis of the ankle and the subtalar joint is disadvantageous as well as the intramedullary position of the implant.
To our knowledge, the above-mentioned treatment method is not described for this indication in the current literature.
In our retrospective study, we compare the outcome of patients with infected non-unions of the distal tibia, who were treated either with retrograde intramedullary nail or with external fixator (golden standard).

Material and method
Patients collective
Patients with an infected non-union of the distal tibia without involvement of the ankle, who were treated with either retrograde intramedullary nail or external fixator between 06/15 and 02/19, are analyzed.
Inclusion criteria are age > 18 years. Exclusion criteria are patients with an ankle empyema or other operative technique.
Epidemiologic data, pre-, peri- and postoperative course will be analyzed. Follow-

up will be analyzed until 12/19.
The primary endpoint is bony fusion of the infected non-union. Secondary endpoints are successful control of infection during follow-up, full weight bearing and the range of motion of the ankle after removal of the intramedullary nail. All kinds of complications will be evaluated.

Surgery
Radical debridements are necessary before implantation of the intramedullary nail. A systemic antibiotic therapy is given at the same time. The chronic osteomyelitis is presumed to be controlled, if the intraoperative samples are sterile.
The cartilage of the ankle and the subtalar joint is not removed. Samples are taken intraoperatively in all patients. After bony fusion, the intramedullary nail is removed; ankle and subtalar joint are released.
Radical debridements as well as a systemic antibiotic therapy are performed in the case of external fixator, too. Chronic osteomyelitis is presumed to be controlled, if the intraoperative samples are sterile.

Statistics:
The treatment methods (external fixator versus retrograde intramedullary nail) are compared and tested for significant differences with regard to primary and secondary endpoints.

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

No

Description IPD sharing plan

clinic specific data

Organizational Data

- DRKS-ID: **DRKS00020552**
- Date of Registration in DRKS: **2020/01/24**
- 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.: **211/2019 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

Health condition or Problem studied

- ICD10: **M86.66 - [generalization M86.6: Other chronic osteomyelitis]**
- ICD10: **M84.16 - [generalization M84.1: Nonunion of fracture [pseudarthrosis]]**

Interventions/Observational Groups

- Arm 1: **Intramedullary nailing with temporary ankle and subtalar arthrodesis in patients with infected non-union of the distal tibia between 06/2015 and 02/2019, retrospective analysis.**
- Arm 2: **External fixation in patients with infected non-union of the distal tibia between 06/2015 and 02/2019, retrospective analysis.**

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

Primary Outcome

Bony fusion

Secondary Outcome

- Control of infection during follow-up
- Full weight bearing
- Range of motion of the ankle and subtalar joint
- complications

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **BG Klinikum Duisburg, Klinik für Orthopädie und Unfallchirurgie, Duisburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/12/18**
- Target Sample Size: **28**
- 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

- Infected non-union of the distal tibia, osteosynthesis with either external fixation or intramedullary nail with temporary arthrodesis of the ankle and subtalar joint

Exclusion criteria

- Ankle empyema
- Other operative techniques (e.g. plate osteosynthesis)

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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  Ms. Dr. med. Eva Steinhausen

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URL: **[---]***

Sources of Monetary or Material Support

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

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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***

Reason, if Reason for Recruiting Stop "Other": **[---]***

- Study Closing (LPLV): **2020/03/31**
- Number of Participants in Germany after Recruiting complete: **28**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **28**

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.*