Trial Description

Title

Evaluation of the clinical effectiveness of bioactive glass (S53P4) in the treatment of non-unions of the tibia and femur: a randomized controlled trial.

Trial Acronym

Bioactive glass in non-union treatment

URL of the trial

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Brief Summary in Lay Language

Treatment of fractures that fail to heal remains difficult. A two-stage therapy was designed to treat these non-healed fractures. In the first stage the affected bone tissue is removed and in the second stage the bone defect needs to be filled with the body's own bone tissue to achieve healing. However, this bone tissue is limited in quantity and an additional surgical procedure is necessary to get this tissue leaving the risk for complications associated with this intervention. Therefore, artificial biomaterials that are able to replace this body's own tissue are needed to prevent the additional surgical intervention. Bioactive glass (S53P4) is a promising biomaterial because it stimulates bone growth and is an effective treatment regarding the prevention of an infection. In the current study, we examine the effectiveness of bioactive glass in the second step of the treatment regarding clinical and radiological outcome when compared with the standard therapy. Patients older than 18 years who suffer from a tibia or femur fracture that failed to healed and receive treatment in our institution are included into the study. The bone defect will be filled in the second step with either bioactive glass (intervention group) or a mix of the body's own bone tissue and a ceramic bone substitute (control group). Hereafter all patients will receive the same standardized follow-up. Primary endpoint of the study is the healing rate of the non-healed fractures 12 months after the treatment.

Brief Summary in Scientific Language

Treatment of non-union of long-bones remain a challenge in orthopaedic and trauma surgery. The Masquelet-therapy (a two-staged procedure) was designed to treat these non-unions. In the first stage the non-union tissue is debrided and in a consecutive second stage the resulting osseous defect needs to be augmented with autologous spongiosa and tricalciumphosphate. However, sources for autologous spongiosa are limited in quantity and procedures associated with harvesting autologous spongiosa are associated with morbidities and complications. Therefore, in the past, research focus shifted towards artificial bone substitutes that are osteostimulative and osteoconductive and might replace autologous spongiosa and prevent the necessity for an additional surgical intervention. Recently bioactive glass with the composition 53% SiO_2, 4% P_2O_5, 23% Na_2O, and 20% CaO has been shown to be both osteostimulative, osteoconductive and antimicrobial making it a promising biomaterial replacing autologous spongiosa. In the current study, we seek to determine the clinical

effectiveness of bioactive glass in the applied non-union treatment. Patients older than 18 years who suffer from a non-union of the tibia or femur and receive the Masquelet-therapy in our institution are included into the study. The osseous defect will be filled in the second step with either bioactive glass (intervention group) or a mix of autologous spongiosa and tricalciumphosphate (control group). Hereafter all patients will receive the same standardized follow-up. Primary endpoint of the study is the union rate of the treated non-union 12 months subsequent to the treatment.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00013882**
- Date of Registration in DRKS: **2018/01/22**
- 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.: **S-472/2017 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M84.15 - [generalization M84.1: Nonunion of fracture [pseudarthrosis]]**
- ICD10: **M84.16 - [generalization M84.1: Nonunion of fracture [pseudarthrosis]]**

Interventions/Observational Groups

- Arm 1: **Intervention group: Patients suffering from a non-union of the tibia or femur treated with the Masquelet-therapy using 100% bioactive glass (S53P4) in the second step of treatment.**
- Arm 2: **Control group: Patients suffering from a non-union of the tibia or femur treated with the Masquelet-therapy using the standard autologous spongiosa and tricalciumphosphate in the second step of treatment.**

Characteristics

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

Primary Outcome

Osseous union achieved 12 months subsequent to treatment

Secondary Outcome

1. Subjective evaluation of the quality of life (assessed by SF-12 questionnaire) and pain (VAS) of affected patients.
2. Perfusion of the graft is evaluated and compared between groups.
3.Expression patterns of inflammatory and angiogenic cytokines are evaluated during the course of the study and compared between groups regarding possible differences.
4. Union achieved two years after surgery
5. Possible differences regarding socioeconomic factors are assessed and compared between groups.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Orthopädie und Unfallchirurgie, Heidelberg**

Recruitment

- Planned/Actual: **Actual**

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- (Anticipated or Actual) Date of First Enrollment: **2018/05/31**
- Target Sample Size: **50**
- 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 older than 18 years who suffer from tibial or femoral non-unions with a bone defect of 2-5 cm³ and who are receiving Masquelet treatment will be included into the study after giving informed consent.

Exclusion criteria

Patients who do not agree to participate in the study, who are not able to give informed consent and patients receiving an amputation because of persistent infection or extended soft tissue defects will be excluded from the study.

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.*