Trial Description

Title

The use of modified collagene membranes compared to PDS foils in orbital floor fractures

Trial Acronym

[---]*

URL of the trial

http://-

Brief Summary in Lay Language

The adequate reconstruction material for orbital floor fractures is discussed in the literature. Common materials Show postoperative complications due to Absorption. Collagene membranes widely used in dental surgery are degraded by collagenases without reactions. Recent studies showed data for clinical use of These membranes. In the present study Collagen membranes will be compared to PDS foils and should demonstrate the equivalent clinical outcome, moreover reduced postoperative symptomes.

Brief Summary in Scientific Language

For orbital floor reconstruction lots of materials are described. PDS foils degraded by citric cycle leads in cases to infection, pain and granuloma and paresthesia. Collagene membranes widely used in dental surgery Show no clinical symptoms due to Degradation. Recent studies showed adequate mechnical properties of collagene membranes for orbital floor reconstruction.

Organizational Data

- DRKS-ID: **DRKS00010809**
- Date of Registration in DRKS: **2016/08/15**
- 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.: **D 427/16 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **S02.3 - Fracture of orbital floor**
- ICD10: **S02.4 - Fracture of malar and maxillary bones**

Interventions/Observational Groups

- Arm 1: **Reconstruction of orbital floor fracture with PDS foils as Standard treatment**
- Arm 2: **Reconstruction of orbital floor fractures with collagene membranes (3 different types) as test Group, each test Group will include 20 participants**

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

The Primary outcome will be reached after 12 month post operationem. In an standardized department specific Investigation bow diplopiae, paresthesia and esthetic probelms will be evaluated.

Secondary Outcome

Infection and Revision of the orbital floor reconstruction

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für MKG-Chirurgie, Kiel**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2016/10/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

isolated orbitalfloor fractures
fractures of the cheek bone

Exclusion criteria

not interested in participation
younger than 18 years
dementia
large fracture with Need of titanium mesh reconstruction

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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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.*