Trial Description

Title

A multicenter randomized controlled trial to investigate the treatment outcome of PHILOS Screw Augmentation compared to PHILOS without augmentation in older adult patients with proximal humerus fractures

Trial Acronym

Philos+

URL of the trial

[---]*

Brief Summary in Lay Language

Comparison of two treatment systems (plates) to roperativen treatment of bone fractures in the area of the proximal humerus

following plates will be compared:
• Proximal Humeral (PHILOS) : A construction of an anatomically shaped plate and screws

• Proximal Humeral Plate with option for augmentation (PHILOS +): A construction of an anatomically molded plate and screws in addition a special bone cement is applied by the

It will involve a total of about 144 people in the study
We will record the medical history of the patient, well-being and potential acute or chronic diseases. After the operation , and at all follow-up questionnaires to be filled out by the patient. These included questions on general health , quality of life , functional ability of the arm and eventual pain.
Duration of study : 12 months recruitment , 12 months follow-up
A total 4 follow-ups are performed: after 6 weeks , 3, 6 and 12 months. Before the operation, by default, a computed tomography (CT) of the shoulder is performed. A total of 12 routine radiographs are made , namely 2 per recordings before and after surgery, and at each follow-up.

The patient is treated with either Philos without cement application or with Philos with cement application . Which of the methods of operation is used in , decides a previously defined random process , comparable to the toss of a coin , a procedure called randomization. The attending physician receives before surgery numbered , sealed and opaque envelopes containing either the phrase " Philos without augmentation or Philos with augmentation. Has your surgeon during their surgical procedure made sure that the upper arm fracture for a supply of the Philo plate is suitable , it opens a envelope to learn about the procedures whereby they are assigned . the probability of a supply by " Philos disk without cement application " or to get by " Philo plate with cement application " , is 50 %. will the patient be allocated to the process with cement application is before application of the cement , a so-called leakage test performed in order (with very thin liquid contrast agent) to ensure that the cement does not flow into the joint space . If this is the

case , erhät the patient in each case, the Philo disk without cement.

Brief Summary in Scientific Language

A multicenter randomized controlled trial to investigate the treatment outcome of PHILOS Screw Augmentation compared to PHILOS without augmentation in older adult patients with proximal humerus fractures

Organizational Data

- DRKS-ID: **DRKS00005261**
- Date of Registration in DRKS: **2014/01/15**
- Date of Registration in Partner Registry or other Primary Registry: **2013/02/05**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **403/13 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Primary Registry-ID: **NCT01847508 (ClinicalTrials.gov)**
- Other Secondary-ID: **[---]***

Health condition or Problem studied

- Free text: **Proximal humerus fractures**
- ICD10: **S42.20 - [generalization S42.2: Fracture of upper end of humerus]**

Interventions/Observational Groups

- Arm 1: **Patient treated with Philos Augmentation**
- Arm 2: **Patient treated without Philos Augmentation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Any occurrence of radiographically confirmed mechanical failure during the first year after treatment

Secondary Outcome

Shoulder function (QuickDASH, SPADI, Constant Score), via Questionnaire and test postoperatively, 6 weeks, 3months, 6 months, 1 Year

Quality of Life (EQ-5D) via Questionnaire postoperatively, 6 weeks, 3months, 6 months, 1 Year

Intra- and postoperative adverse events related to the pro-cedure and/or device, postoperatively, 6 weeks, 3months, 6 months, 1 Year, via questionnaire

Countries of recruitment

- CH **Switzerland**
- AT **Austria**
- DE **Germany**
- BE **Belgium**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**
- Medical Center **Stadtspital Triemli, Zürich**

- Medical Center **Luzerner Kantonsspital, Luzern**
- Medical Center **Charite, Berlin**
- University Medical Center **Universitästklinik des Saarlandes, Homburg**
- University Medical Center **Universitätsklinik Innsbruck, Innsbruck**
- Medical Center **Leuven**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/30**
- Target Sample Size: **144**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **65 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

≥ 65 years
Low energy trauma (eg, fall from standing height)
Radiologically confirmed closed fracture (≤ 10 days) of the proximal humerus
Any displaced or unstable 3- or 4-part fracture of the proximal humerus (ie, segment displacement >0.5 cm or angulated > 45°) except isolated displaced fractures of the greater or lesser tuberosity
Primary fracture treatment with a PHILOS plate
Ability to understand the content of the patient information / informed consent form
Willingness and ability to participate in the clinical investigation including imaging and follow-up procedures (FUs)
Signed informed consent

Exclusion criteria

Bilateral or previous proximal humerus fractures on either side
Splitting fracture of the humeral head or humeral head impression fracture
Cuff-arthropathy of the contra- or ipsilateral proximal humerus
Associated nerve or vessel injury
Any known clotting disorders, severe cardiac and/or pulmonary insufficiency
Known hypersensitivity or allergy to any of the components of Traumacem V+ Cement Kit
Any severe systemic disease: class 4 - 6 of the American Society of Anesthesiologists (ASA) physical status classification
Any not medically managed severe systemic disease: class 3 of the ASA physical

status classification
Recent history of substance abuse (ie, recreational drugs, alcohol) that would preclude reliable assessment
Prisoner
Participation in any other medical device or medicinal product study within the previous month that could influence the results of the present study
Intraoperative decision to use implants other than PHILOS/PHILOS Screw Augmentation

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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

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.*