Trial Description

Title

Clinical, functional and psychosocial outcome of reverse shoulder arthroplasty - a prospective randomized comparison of two types of prostheses after traumatic fracture of the proximal humerus

Trial Acronym

CEUS #Delta

URL of the trial

[---]*

Brief Summary in Lay Language

Fractures of the upper arm close to the shoulder joint are frequent. In these cases there is not only a comminuted fracture but also a disturbed integrity of the muscles framing the shoulder (rotator cuff). Thus, reverse shoulder arthroplasty (RSA) is the treatment of choice in cases of complex fractures of the shoulder in elderly persons. In this kind of treatment the complete joint is replaced including socket and head.
There are two types of prostheses for RSA - type B is used for both plannend RSA treating osteoarthritis of the shoulder and for acute treatment after traumatic injury. Type A was developped especially for acute fracture treatment allowing for refixation of the rotator cuff.
In this study, the clinical and functional outcome of the shoulder of patients after implantation of prothesis type A and type B will be compared.

Patients will be assigned randomly to either type.

In follow-up examinations 6 and 24 months after joint replacement, the range of motion and strength of the shoulder will be tested. Also, a questionnaire will assess the psychosocial outcome.

After RSA, the total length of the upper arm is slightly elongated and the rotational center is shifted. Thus, the deltoid muscle covering the shoulder is stretched and assists to move the shoulder. Therefore, 6 and 24 months after RSA, the deltoid muscle will be examined using contrast-enhanced ultrasound (CEUS) in order to visualize the vitality of the deltoid muscle and complete the functional examination of the shoulder.

Participants of this study are patients with severe fractures of the upper arm that require RSA. Patients with RSA due to degenerative joint disease of the shoulder will serve as a control group.

Brief Summary in Scientific Language

Comminuted fractures of the proximal humerus in elderly persons require reverse shoulder arthroplasty (RSA). Recently developed types of fracture prostheses

allow to bring in bone graft from the patients´ humerus, thus supporting the healing of the refixated tubercula. The Intention is to support the (partial) recovery of the rotator cuff and hence to improve the clinical outcome after surgery.
In this study the clinical and functional outcome of patients receiving RSA using the fracture prosthesis will be compared with the outcome of those receiving a regular RSA prosthesis.

Patients will be assigned randomly to either type.

In follow-up examinations 6 and 24 months after joint replacement, the range of motion and strength of the shoulder will be tested. Also, a questionnaire will assess the psychosocial outcome.

After RSA, a medial shift of the rotational center enables the deltoid muscle to compensate for the deficient rotator cuff. By increasing the tension of the deltoid muscle (lengthening of the humerus) a partial functional restoration of the shoulder can be achieved.
The integrity of the deltoid muscle is highly relevant for a successful outcome after RSA. Its assessment is possible by using contrast-enhanced ultrasound (CEUS) which quantifies the microvascular muscle perfusion. Therefore, 6 and 24 months after RSA, the deltoid muscle will be examined using CEUS in order to complete the functional examination of the shoulder.

Participants of this study are patients that need RSA consequently to traumatic injury. Patients with RSA due to rotator cuff arthropathy (RCA) will serve as a control group.

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

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00011581**
- Date of Registration in DRKS: **2017/01/18**
- 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-626/2014 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1191-4781**

Health condition or Problem studied

- ICD10: **S42.21 - [generalization S42.2: Fracture of upper end of humerus]**
- ICD10: **M19.91 - [generalization M19.9: Arthrosis, unspecified]**

Interventions/Observational Groups

- Arm 1: **Patients with RSA (reverse shoulder arthroplasty) after traumatic injury - model 'fracture prothesis' (with cavity for bone graft)**
- Arm 2: **Patients with RSA (reverse shoulder arthroplasty) after traumatic injury - model 'conventional prothesis'**
- Arm 3: **Patients with RSA (reverse shoulder arthroplasty) due to rotator cuff arthropathy and other osteoarthrisis of the shoulder (planned intervention) - non-randomized control group**

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

**Shoulder function: Constant-Murley-, ASES-, DASH-Score, Simple Shoulder Test;
Psychosocial outcome: SF-12;
Pain: visual analogue scale;
radiological outcome: x-ray;
6 and 24 months postoperatively**

Secondary Outcome

Development of the perfusion in deltoid muscle tissue, assessed with contrast-enhanced ultrasound; 6 and 24 months postoperatively

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Unfallchirurgisches Department, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/12**
- Target Sample Size: **60**
- 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 with multifragmentary fracutres of the proximal humerus and indication of RSA. Patients with rotator cuff arthropathy and indication of planned RSA.

Exclusion criteria

- known intolerance for SonoVue
- severe heart failure (NYHA III/IV)
- myocardial infarction within the last 14 days
- severe respiratory diseases
- pregnancy and breastfeeding
- age under 18 years

Addresses

- **Primary Sponsor**

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■ **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 complete, follow-up continuing**
- 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.*