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

Trial Description

Title

5 year follow-up after reverse shoulder arthroplasty (RSA) of the new generation (Delta XTEND)

Trial Acronym

RSA

URL of the trial

[---]*

Brief Summary in Lay Language

from 2003 to 2014 about 664 reverse shoulder arthroplasties werde performed in th St. VInzenz Klinik. Since 2006 we used the new generation (Delta Xtend, LIMA SMR). The reverse shoulder arthroplasties are performed within patients with not repairable rotator cuff lesions or a special type of joint arthrosis. While there are long term follow-ups for the 1st and 2nd generation of implants, there is no middle to long term follow up for the newest generation.
Aim of the study was to measure the clinical outcome and survival of the prosthesis in mid-term (5 years) and long term(10 years).
We acquired questionnaire based and clinical results pre- 1 year and 5 years post-op. Also xray 1 year and 5 years post-op were performed. 10year follow up is planned.

Brief Summary in Scientific Language

from 2003 to 2014 about 664 reverse shoulder arthroplasties werde performed in th St. VInzenz Klinik. Since 2006 we used the new generation (Delta Xtend, LIMA SMR). The reverse shoulder arthroplasties are performed within patients with not repairable rotator cuff lesions or a special type of joint arthrosis. While there are long term follow-ups for the 1st and 2nd generation of implants, there is no middle to long term follow up for the newest generation.
Aim of the study was to measure the clinical outcome and survival of the prosthesis in mid-term (5 years) and long term(10 years).
We acquired questionnaire based and clinical results pre- 1 year and 5 years post-op. Also xray 1 year and 5 years post-op were performed. 10year follow up is planned.

We acquired the CMS (constant-murley-score), SST (simple shoulder test), patients satisfaction and Range of Motion.
Voluntary patients could decide to do an xray-control.

Organizational Data

- DRKS-ID: **DRKS00007556**
- Date of Registration in DRKS: **2015/01/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Universal Trial Number (UTN): **U1111-1164-6136**

Health condition or Problem studied

- ICD10: **M19.01 - [generalization M19.0: Primary arthrosis of other joints]**
- ICD10: **T84.1 - Mechanical complication of internal fixation device of bones of limb**

Interventions/Observational Groups

- Arm 1: **all implanted RSA of the new generation were pre-op, 1, 5 and 10 years after operation were evaluated using Constant score, clinical examination, force meassurement. radiologic controls were done when wished from the patient**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

baseline, 1, 5 and 10 years after operation, CMS (pre and 1 year post-op through

validated german questionnaire, after 5 years clinical score with force measurement). In addition the SST is acquired via questionnaire. Satisfaction was asked with school marks (1-6). X-ray controls were taken pre- and 1 year post-op standardised. After 5 years, patients could decide to get a voluntary xray.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St.Vinzenz-Klinik, Pfronten**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/02/01**
- Target Sample Size: **76**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Implantation of a RSA in
1. Cuffarthropathy
2. Omarthrosis wth RC-tears,
3. post-traumat. arthrosis with Rotatorcuff insufficiency
4. Problem depending on ohter kind of Implant

Exclusion criteria

death, not reached

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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URL: **http://www.vinzenz-klinik.de**

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.*