Trial Description

Title
Surgical treatment of basal thumb osteoarthritis using the ARPE-prosthesis

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
In basal thumb osteoarthritis, a surgical procedure can be considered if conservative treatment cannot relieve the symptoms. This is often done by removal of a carpal bone. As the space might lead to shortening of the thumb with loss of strength and altered shape, a prosthetic implant can stabilise the joint. The ARPE-prosthesis has been used in Europe for several years. We want to follow the healing process over the course of one year after implantation.

Brief Summary in Scientific Language
The trapezectomy is one of the most commonly performed operations for the treatment of basal thumb osteoarthritis. The Os trapezium is removed completely which results in pain relieve and improvement of function that was impaired by pain. But stability and strength of the thumb is reduced. The sinking of the first metacarpal bone into the space previously filled by the Os trapezium is believed to be the cause. Therefore, modifications fo the trapezectomy were developed to maintain the stability of the thumb. One of the most common modifications is the Epping-resection arthroplasty. The prosthetic replacement of basal thumb joint aims to prevent the shortening, provide stability and reduce iatrogenic damage to the surrounding tissue. We want to prospectively evaluate the clinical and radiological course over one year postoperatively as there are only retrospective studies.

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

Description IPD sharing plan
data will be made available upon request

Organizational Data

DRKS-ID: DRKS00020349
DRKS-ID: **DRKS00020349**

- Date of Registration in DRKS: **2019/12/30**
- 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.: **BB187/18 , Ethikkommission an der Medizinischen Fakultät der Ernst-Moritz-Arndt-Universität Greifswald**

**Secondary IDs**

- Universal Trial Number (UTN): **U1111-1245-4130**

**Health condition or Problem studied**

- **ICD10:** **M18 - Arthrosis of first carpometacarpal joint**

**Interventions/Observational Groups**

- **Arm 1:** **Patients who will receive a ARPE-prosthesis for basal thumb osteoarthritis will be followed over one year postoperatively and examined at defined time intervals.**

**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:** **IV**
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** **N/A**

**Primary Outcome**
The patients will report pain severity of the basal thumb joint during rest and during stress on a scale from 0-10
1. preoperatively
2. postoperatively at least one year after the operation
The values will be compared using the Wilcoxon-test.

Secondary Outcome
range of motion compared to preoperative values, complications

Countries of recruitment

- DE Germany

Locations of Recruitment

- Medical Center Unfallkrankenhaus, Berlin
- Medical Center Klinikum am Urban, Vivantes, Berlin

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2020/01/07
- Target Sample Size: 40
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria
basal thumb osteoarthritis, consent

Exclusion criteria
previous operation on the thumb, inflammatory/rheumatoid joint disease, language barrier
Addresses

- **Primary Sponsor**
  
  Klinik für Unfallchirurgie, Universitätsmedizin Greifswald  
  Mr. Dr. med. Simon Kim  
  Ferdinand-Sauerbruch-Str. 1  
  17475 Greifswald  
  Germany  
  
  Telephone: +4917630734911  
  Fax: 03834866102  
  E-mail: kims at uni-greifswald.de  
  URL: http://www2.medizin.uni-greifswald.de/unfallch/

- **Contact for Scientific Queries**
  
  Klinik für Unfallchirurgie, Universitätsmedizin Greifswald  
  Mr. Dr. med. Simon Kim  
  Ferdinand-Sauerbruch-Str. 1  
  17475 Greifswald  
  Germany  
  
  Telephone: +4917630734911  
  Fax: 03834866102  
  E-mail: kims at uni-greifswald.de  
  URL: http://www2.medizin.uni-greifswald.de/unfallch/

- **Contact for Public Queries**
  
  Klinik für Unfallchirurgie, Universitätsmedizin Greifswald  
  Mr. Dr. med. Simon Kim  
  Ferdinand-Sauerbruch-Str. 1  
  17475 Greifswald  
  Germany  
  
  Telephone: +4917630734911  
  Fax: 03834866102  
  E-mail: kims at uni-greifswald.de  
  URL: http://www2.medizin.uni-greifswald.de/unfallch/

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**
  
  Klinik für Unfallchirurgie, Universitätsmedizin Greifswald  
  Mr. Dr. med. Simon Kim  
  Ferdinand-Sauerbruch-Str. 1  
  17475 Greifswald
Institutional budget, no external funding (budget of sponsor/PI)

Klinik für Unfallchirurgie, Universitätsmedizin Greifswald
Mr. Dr. med. Simon Kim
Ferdinand-Sauerbruch-Str. 1
17475 Greifswald
Germany

Telephone: +4917630734911
Fax: 03834866102
E-mail: kims at uni-greifswald.de
URL: http://www2.medizin.uni-greifswald.de/unfallch/

Status

- Recruitment Status: Enrolling by invitation
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) Studienprotokoll

* 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.