Trial Description

Title

Clinical and functional outcome of the GEMINI SL Fixed Bearing PS Knie-Endoprothese in short-, mid- and longterm follow-up

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

Aim of the PMCF is to confirm the longterm safety and performance of GEMINI SL Fixed Bearing PS knee prothesis which is already CE certificated and sold for several years in a multicentre study.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013892**
- Date of Registration in DRKS: **2018/01/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **AS 157(bB)/2017 , Ethik-Kommission der Landesärztekammer Brandenburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M17 - Gonarthrosis [arthrosis of knee]**
- ICD10: **M87.06 - [generalization M87.0: Idiopathic aseptic necrosis of bone]**
- ICD10: **M87.26 - [generalization M87.2: Osteonecrosis due to previous trauma]**
- ICD10: **M87.96 - [generalization M87.9: Osteonecrosis, unspecified]**
- ICD10: **M12.06 - [generalization M12.0: Chronic postrheumatic arthropathy [Jaccoud]]**
- ICD10: **M12.56 - [generalization M12.5: Traumatic arthropathy]**

Interventions/Observational Groups

- Arm 1: **All patients which are foreseen for an implantation of the GEMINI SL Fixed Bearing PS knee prosthesis, are potential participants of the study. If the patient give informed consent to praticipate in the study, he will be invited to 6 months, 1 and 3 years follow-ups after after initial surgery. Additionally, the patient will be called for an telephone interview after 5 and 10 years.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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

10-year survival rate of the GEMINI SL Fixed Bearing PS with revision for any reason as the endpoint

Secondary Outcome

6 month, 1-, 3. and 5 -year survival rate of the GEMINI SL Fixed Bearing PS with revision for any reason as the endpoint
Evaluation of the functional and clinical outcome from pre- to postoperative follow-ups after 6 month, 1-, 3, 5 and 10-years by using the KSS score
- Complications and revisions

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Krankenhaus Märkisch-Oderland Klinik für Orthopädie , Sportmedizin und Rehabilitation, Wriezen**
- Medical Center **Klinikum Südstadt Rostock Abteilung für Unfallchirurgie und Orthopädie, Rostock**
- University Medical Center **Waldkrankenhaus "Rudolf Elle" GmbH, Klinik für Orthopädie und Unfallchirurgie, Eisenberg**
- Medical Center **Charité, Centrum für Muskuloskeletale Chirurgie, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/04/24**
- Target Sample Size: **250**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- Signed Patient informed consent
- Implantation of a GEMINI SL Fixed Bearing PS knee prosthesis
- age between 18 and 75 years

Exclusion criteria

- Body Mass Index (BMI) > 40 kg/m2
- poor general health with an expected life expectation under 5 years
- known comorbidities and medical conditions, which foreseeable affect the clinical and functional outcome of the knee prosthesis, eg. neurological and musculosceletal disorders

Addresses

■ **Primary Sponsor**

Waldemar Link GmbH & Co KG.
Barkhausenweg 10
22339 Hamburg
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **studies at linkhh.de**
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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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.*