Trial Description

Title

Functional outcome and patient satisfaction after unilateral knee arthroplasty - is computer assisted surgery clinically advantageous?

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

A unilateral knee arthoplasty is a good alternative to a total knee arthroplasty for patients with unicompartmental knee osteoartitis. Besides conventional surgical methods unilateral knee artoplasty can be operated by the means of computer assisted navigation. Studies show that in contrast to navigated protheses, conventional implantation methods can lead to 30% positioning inaccuracies. However, in unilateral knee arthroplasty, optimal positioning of the prothesis components and preservation of an ideal patient individual lower limb alignment is crucial. In the meantime, surgical success after implantation of a unilateral knee arthroplasty is not only judged by the complication rate or wear of the prothesis. The patient´s subjective view comes to the fore. Currently available literature about conventional surgery methods versus computer assisted navigation techniques in unilateral knee arthroplasty lacks satisfactory comparison data regarding functionality and patient satisfaction dependent on the operation method. Aim of this investigation is therefore the comparison of both surgical methods for unilateral knee arthroplasty in terms of functional outcome and patient satisfaction.

Brief Summary in Scientific Language

Unilateral knee arthroplasty (UKA) is a good alternative to a total knee arthroplasty (Perkins et a. 2002; Lorbach et al. 2014) or high tibial osteotomy (Schai et al. 1998) in patients with isolated unicompartmental knee osteoarthritis. Currently 8% of all knee arthroplasties are UKA (Braun 2013). Due to the growing number of younger people with clinically relevant knee osteoarthritis (Fitz et al. 2009), the indication for UKA surgery is increasing. UKA surgery is highly demanding (Manzotti et al. 2014), and its success depends in large parts on the precision of implant positioning, and preservation of an optimal lower limb alignment (Weber et al. 2013, Keene et al. 2006, Rosenberger et al. 2008). However, conventional operation techniques can lead to implant positioning inaccuracies of 30% (Jenny & Boeri 2003). Computer assisted navigation systems were originally developed for total knee arthroplasty (Jenny 2007). However, those navigation systems are also utilized in UKA surgery today. The use of navigation systems is known to show more precise implant positioning than conventional freehand operation techniques (Weber et al. 2013, Song et al. 2016, Weber et al. 2012, Rosenberger et al. 2008, Keene et al. 2006, Jenny 2007). Until recently, surgery success after implantation of an artificial joint was judged by

criteria like wear, complication rates, and mortality (Allvin et al. 2012). In the past years, the clinical outcome and subjective patient view came to the fore (Allvin et al. 2012). Whether the more precise implant positioning trough the use of a navigation system shows also better clinical outcomes and leads to greater patient satisfaction than conventionally operated UKA is not fully clarified (Song et al. 2016, Weber et al. 2013, Seon et al. 2009). The aim of this study is to compare with surgical methods for UKA in terms of functional outcome and patient satisfaction.

Organizational Data

- DRKS-ID: **DRKS00011627**
- Date of Registration in DRKS: **2017/01/31**
- 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.: **144/2016 , Medizinische Ethikkommission der Carl von Ossietzky Universität Oldenburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **M17.1 - Other primary gonarthrosis**

Interventions/Observational Groups

- Arm 1: **Patients of the University Hospital for Orthopedics and Trauma Surgery Pius-Hospital, Medical Campus University of Oldenburg, who were provided with a medial unicompartmental knee arthroplasty (Model UnivationX) - either conventional or by the means of a navigation system - will once be clinically and functionally examined. Additionally, patients fill out self reported questionnaires to evaluate their subjective impression of their knee function, quality of life, and satisfaction. Moreover, complication rate and adverse events ralating to the unilateral knee prothesis will be analyzed. Already existing post-operative radiographs will be utilized to calculate the lower limb alignment.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
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Allocation: **Single arm study**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Differences between navigated and conventional operated knees regarding clinical outcome and patient satisfaction. The following parameters will be evaluated: active and passive range of motion as well as anterior, medial, and lateral knee stability. All clinical tests will be done in a side-to-side comparison manner between the operated and non-operated knee. Knee range of motion will be assessed utilizing a goniometer. Stability assessment will include the Lachmann-test for anterior stability as well as valgus/varus tests for medial/lateral knee stability. Additionally, knee function will be objectively assessed utilizing the Timed up and Go-Test and subjectively with the Oxford Knee Score and Knee Osteoarthritis Outcome Score - Physical Function Short Form. Patient satisfaction will be assessed with the EQ-5D-3L.

Secondary Outcome

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Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Orthopädie und Unfallchirurgie Pius-Hospital, Medizinischer Campus Uni Oldenburg, Oldenburg**

Recruitment

- Planned/Actual: **Actual**

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- (Anticipated or Actual) Date of First Enrollment: **2017/01/23**
- Target Sample Size: **44**
- 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

1. Patients provided with a unicompartmental knee arthroplasty in Pius-Hospital between 2014 to 2016.
2. Age >18
3. signed informed consent form

Exclusion criteria

Inability to properly understand, read, and/or write German.

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 complete**
- Study Closing (LPLV): **2017/03/26**

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.*