Trial Description

Title

Conservative therapy of medial knee osteoarthritis - A prospective randomized study about two different orthosis: 1. ankle foot orthosis versus 2. unloader knee orthosis

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The present study should examine the effect of two different orthosis on patients with osteoarthritis at the medial side of the knee joint.
Several studies have shown that knee orthosis have an effect on complaints of patients with osteoarthritis at the medial side of the knee joint.
A disadvantage of these orthosis are skin irritations at the knee joint. These skin irritations were the cause for discontinuation of the therapy in some patients.
Therefore, a new foot ankle orthosis has been developed. A biomechanical study has shown that this foot ankle orthosis can unload the medial compartment of the knee joint.
The present study should examine if this new orthosis has also an effect on pain and complaints of patients with a unicompartimental osteoarthritis (medial osteoarthritis) of the knee joint.**

Brief Summary in Scientific Language

**Osteoarthritis of the knee joint (Gonarthrosis) is one of the most frequent joint diseases causing pain and loss of range of motion ein [Felson et al. 1998]. This disiease is most frequently localized at the medial compartment of the knee (medial osteoarthritis). Cause is a mechanical overloading of the medial compartment due to a varus malalignement. The therapy of the medial gonarthrosis is conservative [OARSI Guideline, McAlindon et al. 2014]: Patient education, weight reduction, activity, pain killer and biomechanical interventions. Biomechanical interventions are orthosis, bandages, or insoles [McAlindon et al. 2014]. There is scientific evidence for all three therapeutocal options [Draganich et al. 2006, McAlindon et al. 2014, Shelburne et al. 2008]. Most conservative treatment modalities act symptomatic. Biomechanical interventions however could stop the progression of osteoarthritis [van Raaij 2010, Sharma et al. 2001]. Biomechanical studies have shown that orthosis can correct the mechnical axis of the lower extremity more effective than insoles [Fantini Pagani et al. 2012]. Orthosis can act directly at the level of the knee joint or indirectly at the level of teh ankle joint. Biomechanical studies have shown that the knee adduction moment can be reduced by knee unoader braces and by ankle foot orthosis [Fantini Pagani et al. 2012, Fantini Pagani et al. 2014].
Aim of the present prospective randomized study is to compare the clinical results**

of these different orthotic concepts.

Organizational Data

- DRKS-ID: **DRKS00009215**
- Date of Registration in DRKS: **2015/08/13**
- 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.: **EA1/069/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **M17.0 - Primary gonarthrosis, bilateral**
- ICD10: **M17.1 - Other primary gonarthrosis**
- ICD10: **M17.2 - Post-traumatic gonarthrosis, bilateral**
- ICD10: **M17.3 - Other post-traumatic gonarthrosis**
- ICD10: **M17.4 - Other secondary gonarthrosis, bilateral**
- ICD10: **M17.5 - Other secondary gonarthrosis**

Interventions/Observational Groups

- Arm 1: **Valgus knee unloader brace, Unloader One OTS (Össur Deutschland GmbH), the orthosis should be used for a minimum of 6 hours per day over the course of the study (6 month).**
- Arm 2: **Valgus foot ankle orthosis (Agilium freestep von Otto Bock), the orthosis should be used for a minimum of 6 hours per day over the course of the study (6 month).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
-

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

- Who is blinded: **assessor, data analyst**
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome measures are subjective assessments of pain at rest, with walking, and sports activity, reported on a numerical scale (0 to 100) [2] at baseline, at 8 weeks, 6 months and 1 year. This parameter was used for the sample size calculation.

Secondary Outcome

1. Subjective assessment of recovery using a seven-point Likert scale
The seven-point (completely recovered, strongly recovered, significant improvement, moderate improvement, little improvement, slightly recovered, worse than ever) Likert scale used in the present study was used previously by Van Linschoten et al. [10] to study the effect of supervised physiotherapy on patients with a patellofemoral pain syndrome. Patients were deemed to have recovered if they rated themselves fully recovered or strongly recovered, whereas those who rated themselves slightly recovered to worse than ever were deemed not to have recovered. This threshold was used to dichotomize perceived recovery into two clear categories: “recovered” and “not recovered”.
Time points: at 8 weeks, 6 months and 1 year

2. Knee osteoarthritis outcome score (KOOS)
The validated German version of the KOOS is self-explanatory and consists of five subscales; pain, symptoms, sports/recreational activities, activities of daily living, and function [11]. Standardized answer options are given (five Likert boxes), and each question is assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale [11,12]. A total score has not been validated and is not recommended [11]. Responders to the treatment will be defined in accordance with the OMERACT/OARSI set of responder criteria [13]. According to these criteria a responder is a patient having an improvement of more than 20% compared with the baseline score for pain (VAS) and function (KOOS).
Time points: at 8 weeks, 6 months and 1 year

3. Skin irritations
All patients are instructed that skin irritations can occur at sites where the pads of the brace press against the skin. In this case the patients should take a photo of

the skin irritation and contact the study center.

4. Compliance
The patients should mark in a notebook how long the orthosis was used per day. This book should be send to the study center when the study is completed. The a priori definition of compliance is when the orthosis was used longer than 42 hours per week (6 hours per day, 7 days per week) [van Raaij et al. 2010].

5. Additional interventions
Additional interventions should be recorded by the patient over the course of the study.

Countries of recruitment

- DE **Germany**
- CH **Switzerland**

Locations of Recruitment

- Medical Center **Martin Luther Krankenhaus, Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/01**
- Target Sample Size: **154**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **35 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Adults aged 35 years and older years suffering from medial OA. Medial OA is defined as pain located at the medial joint space in combination with radiological signs of OA (Grade 1 or higher) [2]. The radiological signs of OA will be assessed on whole leg x rays using the classification stated by Kellgren and Lawrence [8] (Grade 0-IV).

Exclusion criteria

1. No knowledge of the German language, 2. pain which is not caused by medial OA, 3. lateral OA grade I and more, 4. no varus malalignement.

Addresses

- **Primary Sponsor**

  Otto Bock HealthCare Deutschland GmbH
  Mr. Ingo Rembitzki
  Max-Näder-Straße 15
  D–37115 Duderstadt
  Germany

  Telephone: **0049 55278483530**
  Fax: **0049 55278483535**
  E-mail: **ingo.rembitzki at ottobock.de**
  URL: **www.ottobock.de**
- **Contact for Scientific Queries**

  Otto Bock HealthCare Deutschland GmbH
  Ms. Sarah Schröder
  Max-Näder-Straße 15
  D- 37115 Duderstadt
  Germany

  Telephone: **0049 55278483530**
  Fax: **0049 55278483535**
  E-mail: **sarah.schroeder at ottobock.de**
  URL: **www.ottobock.de**
- **Contact for Public Queries**

  Otto Bock HealthCare Deutschland GmbH
  Ms. Sarah Schröder
  Max Näder Str. 15
  D- 37115 Duderstadt
  Germany

  Telephone: **0049 55278483530**
  Fax: **[---]***
  E-mail: **sarah.schroeder at ottobock.de**
  URL: **www.ottobock,de**
- **Collaborator, Other Address**

  Martin Luther Krankenhaus
  Mr. Prof. Dr. Wolf Petersen

Collaborator, Other Address

Martin Luther Krankenhaus
Mr. Prof. Dr. Wolf Petersen
Caspar-Theyß Str. 27-33
14193 Berlin
Germany

Telephone: **030 89553025**
Fax: **030 89553030**
E-mail: **wolf.petersen at pgdiakonie.de**
URL: **www.pgdiakonie.de**

Sources of Monetary or Material Support

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

Otto Bock HealthCare Deutschland GmbH
37115 Duderstadt
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*