DRKS-ID: **DRKS00009677**
Date of Registration in DRKS: **2016/01/26**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Trial Description

Title

Preventing the progression of Osteoarthritis of the knee Grade 2- 3 by mechanical stimulation with high impact physical exercise training device (GALILEO)

Trial Acronym

Prev-OP

URL of the trial

http://overload-prevop.charite.de

Brief Summary in Lay Language

The osteoarthosis of the knee (OAK) is one of most common degenerative diseases resulted from social development as more immobility, overweight / obesity and increasing life expectancy.
Unfortunately there is a lack on scientific knowledge about exactly causes of the OAK as well as about optimized therapy.
The aim of this study is to prevent the progression of OAK by means of an optimized physical training including a psychological self-regulatory intervention.
The study is funded by the Bundesministerium für Bildung und Forschung (BMBF).

Brief Summary in Scientific Language

Main objective of the project is the prevention of clinical and morphological impairment in patients with osteoarthritis of the knee (OAK) introducing a specific physical exercise program achieving cartilage damage prevention. Efficacy and compliance of the non-pharmacological intervention will be improved by a psychological adherence program. The clinical study approves the measures of mechanical intervention on clinical symptoms and provides biological material (synovial fluid, biopsies of synovial membrane, cartilage, muscle) to measure signalling pathways, stem cell stimulation, and analgesic factors, as well as diagnostic information about the microstructure of subchondral bone, cartilage thickness and material property, cartilage surface, joint space narrowing, load distribution on cartilage
and subchondral bone, metabolic marker of bone, cartilage and muscles. Very important is the outcome with respect of muscle force and power, knee stability and change of muscle fibres and satellite cells.
Primary outcome is the WOMAC pain and function score as well as the use of NSARs.
The study is designed as a randomised, controlled, operator blinded, prospective, non-pharmacological intervention study, including 240 males and females at the age of 40-80 years with moderate OAK (Kellgren & Lawrence Grading 2 & 3), stratified for gender and age, in two treatment groups and one control group. In case of a positive outcome of the study a comprehensive prevention program of physical exercise can be implemented in the health system.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009677**
- Date of Registration in DRKS: **2016/01/26**
- 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.: **EA4/027/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **M17 - Gonarthrosis [arthrosis of knee]**

Interventions/Observational Groups

- Arm 1: **High Impact Exercise - Extensor muscle recovery (EMR) by static and dynamic hypertrophy program followed by high impact exercise (HIE) with resistive vibration exercise (RVE), additionally 50% of individuals of the group receive a psychological adherence program (PAP)**

  The physical training takes place twice a week with a duration of 30 minutes over a time period of 12 months. In the second year all individuals receive a home exercise program twice a week with a duration of 30 minutes.

  The psychological adherence program (PAP) starts with a one hour self management training at M0. During the course of study the self management training will be performed at week 3, 27, 50 und 52 by telephone with a duration of 30 minutes.
- Arm 2: **Low impact exercise (LIE) as walking and stretching exercise program, additionally 50% of individuals of the group receive a psychological adherence program (PAP)**

The physical training takes place twice a week with a duration of 30 minutes over a time period of 12 months. In the second year all individuals receive a home exercise programm twice a week with a duration of 30 minutes.

The psychological adherence program (PAP) starts with a one hour self management training at M0. During the course of study the self management training will be performed at week 3, 27, 50 und 52 by telephone with a duration of 30 minutes.

- Arm 3: **Controls without any exercise treatment, additionally 50% of individuals of the control group receive a psychological adherence program (PAP)**

  The psychological adherence program (PAP) starts with a one hour self management training at M0. During the course of study the self management training will be performed at week 3, 27, 50 und 52 by telephone with a duration of 30 minutes.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

symptoms of OA measured by the WOMAC at baseline (month 0), month 6, month 12, month 18, month 24

Secondary Outcome

Frequency, duration and intensity of physical activity measured by means of accelerometers and self reports at M0 M12, M24;
Physical activity measured by Office in Motion Questionnaire (OIMQ) at M0, M6, M12, M18, M24;
Health-related quality of life measured by SF12-SOEP Version at M0, M6, M12, M18, M24;
Depressive symptoms measured by CES-D scale at M0, M6, M12, M18, M24;
Pain today measured by VAS at M0, M6, M12, M18, M24

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/26**
- Target Sample Size: **240**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

• Women and men in the age between 40 and 80 years
• OAK corresponding grad 2 and 3 according to Kellgren and Lawrence score
• pain > 40 mm measured with the 100 mm VAS over a minimum of 50 % of time within the last month
• Written inform consent

Exclusion criteria

• Knee endoprosthesis at any time
• Hip endoprosthesis in the last12 months
• in the last five years: malignant diseases, angina pectoris, intervention of the coronary arteries, thromboembolic events (e.g. acute deep vein thrombosis, stroke, myocardial infarct, absolute arrhythmia, uncontrolled hypertension, occlusion of the retinal artery or –vein)
• Patients are not be able to perform the investigation conform to the protocol
• Patients with cognitive impairment excluding an understanding of the study protocol and /or the self-dependent completion of the questionnaires
• Insufficient understanding of the German language
• participation in an other clinical study at the same time
• existing pregnancy

Addresses

■ **Primary Sponsor**

Charité Universitätsmedizin Berlin
Mr. Prof. Dr. Ertel
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12203 Berlin
Germany

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

■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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- **Collaborator, Other Address**

  Forschungsverbund Osteoarthrose

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **http://overload-prevop.charite.de/verbund/**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Bundesministerium für Bildung und Forschung Dienstsitz Bonn
  Heinemannstr. 2
  53175 Bonn
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2020/12/18**
- Number of Participants in Germany after Recruiting complete: **240**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **240**

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.*