Trial Description

Title

Multi-centre, randomised, controlled, single-blinded clinical trial to prove the effectiveness of an active motion device (CAMOped) for home-use in the treatment of ruptures of the anterior cruciate ligament in addition to standardised physiotherapy rehabilitation.

Trial Acronym

CAn MObility Postoperatively Enhance Direct rehabilitation (CAMOPED)

URL of the trial

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Brief Summary in Lay Language

Clinical study to show the effect of an active motion device for rehabilitation after rupture of the anterior cruiciate ligament in the knee in addition to physiotherapy

Brief Summary in Scientific Language

The multicentre, prospective, randomised, controlled, single-blind clinical trial to prove the superiority of the use of an active motion device compared to single standardised physiotherapy (PT) in patients after surgical intervention for isolated rupture of the anterior cruciate ligament in a trial procedure will recruit 90 to 200 patients in the DACH region. Randomisation is performed centrally in 4 strata (age and Tegner Score), 1:1 each in CAMOped + PT compared to PT alone. In the event of extended surgery being necessary intraoperatively, these patients will be analysed in a separate subgroup. PEP is the difference in intraindividual improvement of knee joint function measured by subjective IKDC and quality of life 6 weeks postoperatively. Long-term follow-up is 24 months. The evaluation is done in an ITT analysis (PEP) and PP (SEPs). Interim analysis is planned, to determine the presumably necessary number of cases for a sufficient meaningful study.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021739**

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- Date of Registration in DRKS: **2020/05/27**
- 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.: **EA4/080/20 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **S83.53 - [generalization S83.5: Sprain and strain involving (anterior)(posterior) cruciate ligament of knee]**

Interventions/Observational Groups

- Arm 1: **Treatment group receives a standardized physiotherapeutic rehabilitation and additionally a continuous active motion device, for use in a home environment daily for 4x 15-30 minutes. The use of the device can start either preoperatively or postoperatively.**
- Arm 2: **Control group receives standardized physiotherapeutic rehabilitation**
- Arm 3: **Subgroup of patients with intraoperatively diagnosed concomitant diseases of the knee joint requiring intervention and a restrictive rehabilitation scheme. Here a comparison of the active and passive motion device, each in addition to the standardized physiotherapy will be performed.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist, assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

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

Primary Outcome

Superiority of the improvement of joint function (range of motion, pain, swelling) in surgical treatment of a rupture of the anterior cruciate ligament through the additional use of an active motion device compared to the sole standardised physiotherapeutic rehabilitation after 6 weeks

Secondary Outcome

Safety, benefit assessment, medical necessity
- Joint function after 3 and 6 weeks and in the long-term after 1 and 2 years (mechanical and functional stability, coordination and proprioception)
- pain reduction after 3 and 6 weeks, change in the intake of pain medication
- effusion regression, wound closure after 3 and 6 weeks
- Achievement of individual targets (Goal attainment scale; GAS)
- Time to return to the ability to work under pressure (sports / ability to work again)
- Reduction of muscle atrophy of the affected quadriceps muscle
- Differences in rehabilitation depending on the chosen surgical procedure (short-term and long-term)
- Frequency, length and step count of use
- Frequency of re-ruptures and surgical interventions or revision interventions
- health-related quality of life, self-confidence
- Time to start physiotherapy, time to reach the predefined 12 physiotherapy meetings
- Economy in domestic use (economic analysis)
- Reduction of disturbed rehabilitation and late complications
- Usability
- Benefit/risk assessment
- Validation of sonography as an additional measuring instrument for therapy decisions and return to sports / competition
- Validation of the modified IKDC 2000 (IKDC-OPED) as a quantifiable measure for an objective decision to return to (competitive) sport
- Non-inferiority of the continuous active motion device compared to the continuous passive motion device in the rehabilitation of patients with intraoperative treatment of a concomitant injury requiring intervention, leading to a change in the post-treatment regimen

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Berlin, Heidelberg, München, Brandenburg an der Havel, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/06/08**
- Target Sample Size: **120**
- 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

planned surgical treatment of a rupture of the anterior cruciate ligament

Exclusion criteria

- Poor compliance or mental disorders
- Non-consentability
- Participation in another clinical study -Acute or chronic injury / restriction of the contralateral side
- Luxation of the knee joint
- Injury to the posterior cruciate ligament (from Schenck II)
- Sideband injury (MSB and LSB) > Grade I
- Cartilage damage in need of intervention that leads to a modification of the post-treatment scheme
- Operation of the lower extremity in the last 6 months
- Recurrent knee surgery, ACL revision surgery
- Neurological diseases
- Basic muscular diseases
- Injuries to the ankle or hip joint
- Clinical Gonarthrosis

- Chronic anteroposterior instability, chronic meniscopathy, cartilage defects or other diseases of the knee joint
- Limitation of movement through surgical procedures
- Postoperative infection (exclusion in ongoing study)
- Condition after deep vein thrombosis of the legs
- Clinically relevant pAVK
- Passive ROM < 70°

Addresses

■ **Primary Sponsor**

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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.*