Trial Description

Title

Anterior Cruciate Ligament Revision Surgery: Ipsilateral Quadriceps Versus Contralateral Semitendinosus-Gracilis Autografts

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The trial has the intention to compare the outcome of the reconstruction of the anterior cruciate ligament. Hypothesis: Quadriceps-tendon grafts have an equal outcome after revision surgery compared with hamstring grafts. On the basis of different scores and tests occurs a examination of the hypothesis.
The group of patients for the trial must have their surgery at least two years ago. Furthermore it has to be their second rupture of the anterior cruciate ligament and the tendon used has to be either a hamstring or quadriceps graft. If there is a treatment indicated after examination surgery or diagnostic radiology is possible.

Brief Summary in Scientific Language

The trial has the intention to compare the outcome of the reconstruction of the anterior cruciate ligament. Hypothesis: Quadriceps-tendon grafts have an equal outcome after revision surgery compared with hamstring grafts. On the basis of different scores (KOOS and Lysholm) and tests (KT-1000 and Pivot-Shift) occurs a examination of the hypothesis.

Organizational Data

- DRKS-ID: **DRKS00006770**
- Date of Registration in DRKS: **2015/03/19**
- 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.: **EA1/004/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **Reconstruction of the anterior cruciate ligament**
- ICD10: **S83.50 - [generalization S83.5: Sprain and strain involving (anterior)(posterior) cruciate ligament of knee]**

Interventions/Observational Groups

- Arm 1: **Patients after reconstruction of the ACL with quadriceps graft: KT-1000 measurement and Pivot-Shift-Test. Use of KOOS- and Lysholm-Score**
- Arm 2: **Patients after reconstruction of the ACL with hamstring graft: KT-1000 measurement and Pivot-Shift-Test. Use of KOOS- and Lysholm-Score**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Parameter:

**Lysholm Score: limp, support,
stair climbing, squatting, instability, pain, swelling**

KOOS Score: Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL).

Timepoint: At least two years after a second rupture of the anterior cruciate ligament and the tendon used has to be either a hamstring or quadriceps graft.

Secondary Outcome

Parameter: KT 1000 measurment and Pivot Shift Test: Anterior stability and dislocation of the knee joint.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

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

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

>18 years, <60 years

Two surgeries of the ACL with grafts already have been done. Second one either with hamstring- or quadriceps-graft.

Exclusion criteria

<18 years, >60 years

Addresses

- **Primary Sponsor**

  Martin-Luther-Krankenhaus

Primary Sponsor

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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): **2015/05/04**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*