Trial Description

Title

Analysis of the lower limb function and the quadriceps anatomy in patients after non-traumatic patella dislocation: An in-vivo study about the relationship between patello-femoral instability and resultant joint kinematiks

Trial Acronym

Patfem Instability

URL of the trial

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Brief Summary in Lay Language

We would like in this study to measure up to 20 subjects for each of the two different groups. Goal of this analysis is the quantification of the knee motion and the description of the anatomy of the flexor mechanisms of the knee joint in patients with a chronic instability of the patello-femoral joint, which manifests itself with a dislocation of the patella. In this group we want to recruit primary patients who are born with a not deep enough trochlea groove at their thigh bone (femur) (trochlea dysplasia). These patients will be compared against a control group that have were born with normal trochlea and have had no dislocations if the patella, as well as with a patient group, which has had surgical stabilization of the patello-femoral joint with a surgical reconstruction of the medial patello-femoral ligament. These comparisons serve the purpose of better understanding the conditions under which a patella dislocation happens, with a further goal to develop new therapies and establish their usefulness. Through the use of new, computer-based biomechanical analysis the diagnosis and development of a treatment approach for these patients should be improved.

Brief Summary in Scientific Language

Patello-femoral instability leads to changes of the joint kinematics, and adaptational processes on the underlying active and passive stabilizators of the patella. The degree of potential adaptation of the quadriceps and the influence on the function of the knee joint, as well as the efficiency to compensate the instability, is not known in patients with patello-femoral instability until now, and constitutes a goal of this study.
Trochlea dysplasia is on of the main risk factors for recurrent instability. The anatomical correction by trochleoplasty is a quit invasive surgical method and is employed primarily for dealing with heavy cases of trochlea dysplasia. As a more appropriate, alternative, method to cope with instability in cases of mild dysplasia is the reconstruction of the medial patello-femoral ligament. Still, it is not known how far the reconstruction of the medial patello-femoral ligament can normalize the in-vivo measured joint kinematics, or whether additional treatment is needed to re-establish the normal kinematics. This is an additional goal of this study.

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

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000332**
- Date of Registration in DRKS: **2010/02/18**
- 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.: **EA1/291/09 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1113-7258**

Health condition or Problem studied

- ICD10: **S83.0 - Dislocation of patella**
- ICD10: **M22.0 - Recurrent dislocation of patella**
- ICD10: **M22.1 - Recurrent subluxation of patella**
- ICD10: **M22.2 - Patellofemoral disorders**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
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Blinding: **[---]***

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

Primary Outcome

Group A:The kinematics of the knee, hip, and ankle joint, as well as the resultant ground reaction foce will be measured pre-operatively, at least 4 weeks after the last dislocation, with the help of gait analysis and VICON software.
Group B: The kinematics of the knee, hip, and ankle joint, as well as the resultant ground reaction foce will be measured at least 12 months post-operatively, with the help of gait analysis and VICON software

Secondary Outcome

Group A: The ratio of the cross-sectional area of the vastus lateralis muscle to the vastus medialis, will be measured pre-operatively, at least 4 weeks after the last dislocation, with the help of MRI imaging of the quadriceps.

Group B: The ratio of the cross-sectional area of the vastus lateralis muscle to the vastus medialis, will be measured at least 12 months post-operatively, with the help of MRI imaging of the quadriceps.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Planned**

Planned/Actual: **Planned**

- (Anticipated or Actual) Date of First Enrollment: **2010/03/01**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **40 Years**

Additional Inclusion Criteria

Group A:
-The patients have proper health insurance
- Trochlea dysplasia Grade A-C
- First dislocation at least 6 months before analysis
- Last dislocation at least 4 weeks before analysis

Group B:
-The patients have proper health insurance

Exclusion criteria

Group A:
- Surgical treatment of the patello-femoral joint
- Additional pathologies of the knee, and the active and passive stabilizators

Group B:
- No other previous surgical intervention for the stabilization of the patello-femoral joint

Addresses

- **Primary Sponsor**

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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.)**

European Commission
Information Society and Media Directorate-General
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URL: **[---]***

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.*