

Trial Description

Title

Kinematics of the Knee after Single Bundle and Double Bundle Anterior Cruciate Ligament (ACL) Reconstruction. A Prospective Randomized Study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The anterior cruciate ligament replacement belongs for years to one of the world's standard procedures in orthopaedics. At the Charite, we perform each year more than 200 of these operations. We are a center with extensive experience in this area. However, it is shown that in spite of this operation some patients experience early osteoarthritis than uninjured patients. The aim of the study is to investigate the motion of the knee joint before and after the operation. Thus, two well-established surgical techniques should be investigated for possible benefits. There have been many studies on the movement of the knee joint, both in patients, as well as in cadaveric knees. Several groups used conventional radiography, magnetic resonance scans (MRI) in order to achieve this goal. But until today it is not possible to reliably predict the position of the knee joint during the motion of the knee. This knowledge is necessary to be able to calculate forces and stresses in the joint. From this data, accurate predictions about the loads of the knee could be made. These findings would influence the development of future surgical techniques and improve the assessment of today's standard procedure.

Brief Summary in Scientific Language

Anterior cruciate ligament (ACL) reconstruction is one of the most common operation with approximately 80,000 performed per year in Germany alone. The ACL can be damaged during sudden dislocation, torsion, or hyperextension of the knee. Compared to other tendons and ligaments, ACL ruptures do not heal, resulting in knee instability even during daily activities and especially during sport activities which cutting and pivoting manouvers. Furthermore, without treatment, the ACL injury can affect the surrounding tissues of the knee such as the menisci and lead to early osteoarthritis. To allow these patients to return to sporting activities, it is necessary to perform reconstructive surgery of the ACL. The ACL consists of two functional bundles, an anteromedial (AM) and a posterolateral (PL) bundle. The AM bundle is responsible for the anterior-posterior stability of the tibia, while the PL bundle is though to assume control of the rotational stability of the knee. Two operation techniques are currently performed to reconstruct the ACL. One is the single bundle technique that reconstructs only the AM bundle. The other surgical procedure is the double bundle technique in which both bundles, the AM and the PL, are reconstructed. Although there is increasing evidence that demonstrates the benefits of double



bundle reconstruction over the single bundle procedure, evidence regarding the dynamic rotational stability of the knee joint after single or double bundle ACL reconstruction is still limited.

The aim of the study is therefore to collect consolidated findings regarding on kinetics, kinematics and biomechanics of the normal, ACL injured and ACL reconstructed knees.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000333**
- Date of Registration in DRKS: **2010/03/25**
- 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.: **EA1/167/08 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1113-7424**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Anterior cruciate ligament single bundle reconstruction, which reconstructs only the anteromedial (AM) bundle.**
- Arm 2: **Anterior cruciate ligament double bundle reconstruction in which both bundles, the anteromedial (AM) and the posterolateral (PL) are reconstructed**

Characteristics



- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: [---]*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Determination of the knee joint kinematics by means of gaitanalysis, computer tomographie and fluoroscopy, preoperative and at 3, 6 and 12 months follow up postoperative

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/09/16**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
-

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Minimum Age: **18 Years**

- Maximum Age: **100 Years**

Additional Inclusion Criteria

Patients with an isolated ACL injury

Exclusion criteria

Previous or multiple injuries of the knee (e.g. collateral ligament insufficiency, damaged meniscus, tibia and/or femur fracture)

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.)**

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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.