

# Results after anterior cruciate ligament reconstruction using the quadriceps tendon with or without a bone block

<b>Submission date</b> 29/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 14/02/2018	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The anterior cruciate ligament (ACL) is a tough band of tissue in the middle of the knee, preventing the shin bone (tibia) from sliding out in front of the thigh bone (femur). It is one of the four main ligaments within the knee, and the most common to be injured. ACL injuries usually happen in young athletes during high-intensity sports such as alpine skiing or soccer. Following an ACL injury, the knee joint itself can become unstable, which may prevent patients returning to their daily life activities. If this is the case, ACL reconstructive surgery is the best treatment option, which involves replacing the injured ACL with a tendon from elsewhere in the body, usually the quadriceps (thigh) and modifying the bone next to the joint to limit the motion of the joint (bone block). However, there is no clear evidence whether harvesting the tendon with or without a bone block of the knee cap has an impact on the clinical outcome. The aim of this study is to look at the outcomes for patients after ACL reconstruction surgery when bone block is also used to those for patients where bone block is not used.

### Who can participate?

Adults who have an ACL injury that requires surgical treatment

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group undergo ACL reconstruction surgery using bone block. This involves modifying the bone next to the joint to limit motion. Those in the second group undergo ACL reconstruction surgery without using bone block. At the start of the study and then again after six, 12 and 24 months, participants in both groups have their knee stability and function assessed as well as completing questionnaires about their recovery and pain levels.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating in this study.

### Where is the study run from?

Gelenkpunkt (Austria)

When is the study starting and how long is it expected to run for?  
June 2016 to January 2020

Who is funding the study?  
Gelenkpunkt (Austria)

Who is the main contact?  
Miss Caroline Hepperger  
c.hepperger@gelenkpunkt.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
QT07102016

## Study information

**Scientific Title**  
Clinical outcomes in anterior cruciate ligament reconstruction using quadriceps tendon autografts with or without bone block: a patient-blinded prospective randomized trial

**Study objectives**  
The anterior tibial translation in patients after anterior cruciate ligament reconstruction using a bone-free quadriceps tendon autograft is postoperatively not more than 1mm compared to patients operated with a quadriceps tendon-bone graft.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Ethikkommission der Medizinischen Universität Innsbruck, 16/11/2016, ref: AN2016-0172 365/4.5

**Study design**

Patient-blinded prospective randomized parallel trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Anterior cruciate ligament injury

**Interventions**

Participants are randomised to one of two groups in a 1:1 ratio using the closed envelope method.

Group 1: Participants receive an anterior cruciate ligament reconstruction using a quadriceps tendon autograft without bone block. This involves harvesting a quadriceps tendon strip (7 x 0.5 cm) of the injured knee.

Group 2: Participants receive an anterior cruciate ligament reconstruction using a quadriceps tendon autograft with bone block. This involves harvesting a bone block (1.5-2cm x 1cm) from the patella at the insertion of the quadriceps tendon. Further fixation and reconstruction of the anterior cruciate ligament is the same as in group 1

Follow up for all participants involves clinical and radiological evaluation and takes place 6, 12 and 24 months post-operatively.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Anterior knee stability is measured using the Lachman test at baseline, 6, 12 and 24 months post-operatively.

**Key secondary outcome(s))**

1. Pain is measured using the visual analogue scale (VAS) at baseline, 6, 12 and 24 months post-operatively
2. Patient-reported outcome is measured using the Lysholm and Tegner score (questionnaire) baseline, 6, 12 and 24 months post-operatively
3. Knee muscle strength is measured using a dynamometer at baseline, 6, 12 and 24 months post-operatively
4. Balance, speed and strength of the lower limb are measured using the "Back in action" test battery at baseline, 6, 12 and 24 months post-operatively
5. Osteoarthritis is measured using x-ray (Kellgren and Lawrence score) at 24 months post-operatively

**Completion date**

01/01/2020

# Eligibility

## Key inclusion criteria

1. Age 18-60 years
2. Diagnosed with anterior knee instability requiring anterior cruciate ligament reconstruction in which the surgeon chose a QTB graft for reconstruction
3. Obtained written consent

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

60 years

## Sex

All

## Key exclusion criteria

1. Patient prefers one surgical technique over the other or does not consent to a surgical treatment at all
2. Pre-existing ipsilateral knee pathology
3. Bilateral ACL injuries
4. Chronic ACL injuries older than 6 months
5. Multiligament injuries (in combination with posterior cruciate or collateral ligament injuries grade II or higher)
6. Chondral injuries (lesions greater than 2cm<sup>2</sup> with a depth of more than 50% of the cartilage thickness)
7. Meniscal injuries (involving more than 2/3 of the meniscus or need for meniscus repair)
8. Infection
9. Systematic disease
10. Lack of compliance
11. Chronic alcohol or drug abuse

## Date of first enrolment

01/01/2017

## Date of final enrolment

31/12/2018

# Locations

## **Countries of recruitment**

Austria

## **Study participating centre**

### **Gelenkpunkt**

Tivoli Ost

Olympiastrasse 39

Innsbruck

Austria

6020

## **Sponsor information**

### **Organisation**

Gelenkpunkt

### **ROR**

<https://ror.org/05aqc8c91>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Gelenkpunkt

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Caroline Hepperger (c.hepperger@gelenkpunkt.com)

### **IPD sharing plan summary**

Available on request