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

Submission date
29/12/2016

Recruitment status
No longer recruiting

Registration date
16/02/2017

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures

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

Overall study start date
01/06/2016

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
50

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 2cm2 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
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Sponsor information

Organisation
Gelenkpunkt

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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05aqc8c91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gelenkpunkt

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2021.

Intention to publish date
31/12/2021

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