Anterior cruciate ligament hamstring study: Hamstring muscle strength after anteromedial portal ACL reconstruction versus tape locking screw ACL reconstruction

Published: 17-01-2017
Last updated: 11-04-2024

The main objective of this study is to compare the hamstring muscle strength deficit after AMP and TLS reconstruction techniques.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43081

Source
ToetsingOnline

Brief title
Hamstring

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Anterior crucial ligament rupture

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ACL, AMP, Hamstring, TLS

Outcome measures

Primary outcome

The main study parameter is hamstring muscle strength deficit. Measured by a

Biodex dynamometer.

Secondary outcome

Not applicable

Study description

Background summary

Anterior cruciate ligament (ACL) reconstruction techniques are developing continuously. Studies have shown that anatomical positioning of the femur tunnel is an important predictor for the clinical outcome. This has led to the development of new reconstruction techniques with a more anatomical placement of the femur tunnel: the anteromedial portal (AMP) ACL reconstruction technique and, more recently, the tape locking screw (TLS) ACL reconstruction technique. Multiple retrospective studies have shown that the use of a the anteromedial portal (AMP) and tape locking crew (TLS) reconstruction technique have a better short term clinical outcome. At this moment, the most widely used technique is the AMP (performed in approximately 80% of the ACL reconstructions). The TLS technique is widely used in France and the available literature shows good short-term results.
A difference between the AMP and the TLS techniques is that the AMP technique uses a double-bundle hamstring graft where the TLS technique uses a single-bundle hamstring graft. The idea is that using a single-bundle hamstring graft causes a less hamstring muscle strength deficit. The available literature shows different outcomes of hamstring muscle strength deficit, although, there are no studies found in which the difference in hamstring muscle strength

deficit between both techniques directly has been investigated.

Study objective

The main objective of this study is to compare the hamstring muscle strength deficit after AMP and TLS reconstruction techniques.

Study design

Retrospective case-controlled pilot study

Study burden and risks

Both intervention operation procedures which are performed are considered safe and effective. The burden for the participants in this study is limited. The follow-up after ACL reconstructive surgery is standardized in our hospital. The participants of this study will undergo the same standardized follow-up. The patient will undergo an additional biodex measurement 12 and 20 weeks after surgery which wil take approximately 45 minutes. There are no risks to the Biodex measurement for the patient. It is a non-invasive test.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patient older than 18 years and younger than 60 years old.
• Mentally competent to understand the informed consent.
• Patient underwent AMP or TLS ACL reconstruction surgery or will be

Exclusion criteria

• ACL reconstruction surgery older than 12 weeks.
• Meniscus rupture larger than 25%
• Indication for meniscal repair.
• Injury of the collateral ligaments or posterior cruciate ligament
• History of ACL or meniscal rupture
• Neurological or systemic disorder that inhibit adequate rehabilitation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2017

Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL60029.075.16