Anterior cruciate ligament CT study: Transtibial, anteromedial portal, tape locking screw reconstruction technique

Published: 16-06-2017
Last updated: 20-04-2024

The main objective of this study is to compare the femur tunnel positioning after AMP, TLS and TT reconstruction techniques. We will also look at the relation between tunnel positioning and tunnel widening.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON40533

Source
ToetsingOnline

Brief title
ACCENT

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
anterior cruciate ligament rupture

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Bedrijven en fondsen,FH Orthopedics is een

Frans bedrijf dat één van de ontwikkelaars is van de TLS techniek. Zij leveren onderanderen het instrumentarium voor het toepassen van deze techniek.

Intervention

Keyword: Anatomical, Anterior cruciate ligament, CT-analysis, Transtibial

Outcome measures

Primary outcome

The main study parameter is the percentage of correct positioned femur tunnels

using CT-analysis.

Secondary outcome

the secondary study parameter is the increase of tunnel diameter 1 year after

surgery using CT-analysis

Study description

Background summary

Anterior cruciate ligament (ACL) reconstruction techniques are continuously changing. Anatomical reconstruction are the latest development. Anatomical femur tunnel positioning has been shown to be an important predictor for the clinical outcome. This has led to the development of new reconstruction techniques. Multiple retrospective studies have shown that the anatomical placement of the femur tunnel with the use of a the anteromedial portal (AMP) and tape locking crew (TLS) reconstruction technique have a better short term clinical outcome. Most studies show a significant difference between the techniques, but not a clinical relevant difference. Randomized controlled trials directly comparing both techniques with the standard transtibial (TT) drilling technique aren*t available. There is now current data comparing the location of the tunnel positioning en widening of tunnels between the three different groups. Tunnel widening has been considered an early sign of graft failure.

Study objective

The main objective of this study is to compare the femur tunnel positioning after AMP, TLS and TT reconstruction techniques. We will also look at the

relation between tunnel positioning and tunnel widening.

Study design

randomised control intervention study

Intervention

ACL reconstruction with autograft or allogaft using AMP en TLS reconstruction technique

Study burden and risks

both intervention operation procedures are considered safe and effective. A recent study using the Danish Knee Ligament Reconstruction Register showed that the AMP technique has a slightly increased risk (RR: 2.01) of revision surgery. This was attributed due to the implementation of this new technique. The surgeons participating in this study are well experienced with the TT and AMP techniques and will be well trained in the TLS technique.
The burden for the participants in this study is minimal. 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 addition CT-scan., 1 year after surgery. The CT-scan will increase the radiation exposure with 0.16 mSV.

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.
- Clinical diagnosis of ACL rupture.

Exclusion criteria

- ACL rupture older than 6 months.
- 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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-12-2017
Enrollment:	87
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43499.075.14