The transtibial vs. anteromedial portal technique for ACL reconstruction: is there a difference in MRI signal intensity of the graft

Published: 15-10-2015
Last updated: 15-05-2024

To conduct a randomised controlled trial to determine differences in outcomes of the TT and AMP ACL reconstruction techniques by means of MRI signal SI of the ACL graft. Secondly, differences in clinical, functional and patient-oriented outcomes of...

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

Summary

ID

NL-OMON44860

Source
ToetsingOnline

Brief title
TRANSIG study

Condition

- Tendon, ligament and cartilage disorders

Synonym
anterior cruciate ligament rupture

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: Maatschap Orthopedie Martini Ziekenhuis

Intervention

Keyword: ACL reconstruction, anatomical, graft signal intensity, transtibial

Outcome measures

Primary outcome

The primary objective of this study is to conduct a randomised controlled trial to determine differences in MRI SIR of the ACL graft following the transtibial (TT) and anteromedial portal (AMP) ACL reconstruction drilling technique.

Secondary outcome

Clinical and functional outcomes will be assessed by The International Knee Documentation Committee (IKDC) Knee Examination Form and patient-oriented outcomes will be assessed by Knee injury and Osteoarthritis Outcome Score (KOOS) assessment.

Additionally, MRI assessment with the current PDWI/PDWI SPAIR imaging protocol will be compared to additional T2*WI gradient echo imaging protocol.

Study description

Background summary

Rupture of the anterior cruciate ligament (ACL) is a frequently seen (sport) injury mostly induced by a non-contact deceleration motion and can be treated by ACL reconstruction surgery. There are two primary surgical techniques to reconstruct the ACL: transtibial (TT) technique or anteromedial portal (AMP) technique. Currently, there is no evidence which surgical technique elicits the best clinical and functional outcomes. However, these assessments are an indirect measure of the graft integrity and require large numbers of patients to detect differences between both operation techniques. There is a need for a quantitative in vivo measurements method for the evaluation of the biomechanical performance of the ACL graft. MRI-derived measures of the signal

intensity (SI) of the ACL graft have been described as an independent predictor of graft properties. MRI assessment with proton density weighted imaging (PDWI) fails to correlate with actual graft function. A more promising technique is T2*-weighted gradient-echo MRI imaging which has been reported as a useful imaging modality to assess graft integrity. This leads to our research question: Is there a difference in SI of the ACL graft on MRI, one year after ACL reconstruction, between TT and AMP reconstruction technique?

Study objective

To conduct a randomised controlled trial to determine differences in outcomes of the TT and AMP ACL reconstruction techniques by means of MRI signal SI of the ACL graft. Secondly, differences in clinical, functional and patient-oriented outcomes of the TT and AMP ACL reconstruction techniques will be assessed. Additionally, differences between MRI SIR assessment with the current MRI protocol (PDWI and PDWI SPAIR imaging protocol) and the additional T2*WI gradient echo protocol will be assessed.

Study design

A randomised controlled trial will be executed. Patients will be randomly allocated to undergo ACL reconstruction by means of the TT and AMP drilling technique. The trial will be conducted at the department of Orthopaedics of the Martini Hospital Groningen.

Intervention

Patients in the study group will undergo ACL reconstruction using the AMP technique. This technique will be compared to the conventional TT technique for ACL reconstruction in the control group.

Study burden and risks

Since both the TT and AMP technique for ACL reconstruction are standard techniques for ACL reconstruction, no additional risks are associated with participation of the study. No additional risks are involved with the MRI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 18 and 60 years
- A proven ACL rupture confirmed by means of arthroscopy or MRI scan

Exclusion criteria

- a history of previous surgery on the ipsilateral knee
- re-rupture of the ipsilateral ACL graft
- associated ligamentous injuries or meniscal tear of the ipsilateral knee
- unhealthy contralateral knee
- contra-indications for MRI
- preference for one of the two surgical techniques and/or orthopaedic surgeon

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2016
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	27-06-2017
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28419
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54568.099.15
OMON	NL-OMON28419