MRI signal intensity of ACL graft following ACL reconstruction (TRANSIG study)

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28419

Source
Nationaal Trial Register

Brief title
TRANSIG

Health condition

Voorste kruisband reconstructie
Anterior cruciate ligament reconstruction

Sponsors and support

Primary sponsor: Department of Orthopaedics
Martini Hospital
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to conduct a randomised controlled trial to determine

differences in outcomes of both the anteromedial portal (AMP) and transtibial (TT) ACL reconstruction technique by means of the MRI SIR of the ACL graft.

Secondary outcome

Differences in functional and clinical outcomes between the AMP an TT ACL reconstruction technique will be assessed by means of the standardized physical examination and recorded by the use of the International Knee Documentation Committee (IKDC) Knee Examination Form. Differences in patient-oriented outcomes between the AMP an TT ACL reconstruction technique will be assessed by the use of the Knee injury and Osteoarthritis Outcome Score (KOOS). 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 description

Background summary

Rationale:

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?

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.

Study population:

Patients who are admitted for primary unilateral ACL reconstruction will be included in the study.

Intervention (if applicable):

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.

Main study parameters/endpoints:

SIR of the ACL graft will be assessed by the use of the PDWI and T2*WI MRI imaging protocol. 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 PDWI imaging protocol will be compared to T2*WI gradient echo imaging protocol.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

Study objective

It is hypothesized that the anteromedial portal (AMP) technique would result in lower MRI signal intensity and thereby better graft maturity due to the better rotational stability compared to the conventional transtibial (TT) technique.

Study design

The MRI images will be obtained one year postoperatively.
Secondary outcomes by means of the IKDC examination and KOOS measurements will be obtained at preoperative and 12 months postoperatively by an independent investigator.
Patients will have regular follow-up with outpatient clinic appointments.

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.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 18 and 50 years

- A proven ACL rupture 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2015
Enrollment:	36
Type:	Unknown

Ethics review

Positive opinion

Date:	24-08-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44860
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5301
NTR-old	NTR5410
CCMO	NL54568.099.15
OMON	NL-OMON44860

Study results