MRI assessment and patient specific biomechanical modelling of ACL deficient knees to improve ACL reconstructive surgery; a feasibility study.

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

Summary

ID

NL-OMON42444

Source
ToetsingOnline

Brief title
MRI based modelling of ACL reconstruction

Condition

- Tendon, ligament and cartilage disorders

Synonym
ACL Rupture, Torn ligament

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: European Research Council (ERC)

Intervention

Keyword: ACL reconstruction, Feasibilty study, Finite Element Model, Porto-Knee Testing Device

Outcome measures

Primary outcome

The main parameters (antero-posterior and rotational laxity) will be statistically analyzed using a t-test or a paired t-test. The difference in rotation due to the attachment sides will be analyzed using Spearmen correlation. Additionally, regression analysis is used to determine the reliability of the clinical tests compared to the PKTD. Because, this is a feasibility study all p-values generated in hypothesis testing will be interpreted within the context of an explorative study.

Secondary outcome

n.v.t

Study description

Background summary

Many musculoskeletal diseases, such as ACL ruptures, are related to biomechanical factors. The tools used by clinicians and researches to assess the biomechanical condition of patients, such as Lachman test and MRI, are often crude and subjective, leading to non-optimal patient analyses and care. A recently developed tool; Porto Knee Testing Device, was found reliable in quantitative assessment of knee laxity, using simple distance parameters. MRI based FE analysis in clinical environment has become more promising over the last years. Using these 3D computer models in addition to the MRI PKTD scans, it could give more information about the deficient ACL, and/or about the reconstruction. However, no studies ever have combined the PKTD with MRI based

FE models.

Study objective

The aim of this study is to image and model patient specific ACL-deficient knees applying several developed methods, to determine the feasibility of PKTD and MRI based FE models in assessing knee laxity in ACL-deficient knees before and after reconstruction, and to determine the influence of the ACL attachment sides on mechanical performance of the knee joint. The additional aim is to determine the reliability of assessing knee laxity using the PKTC compared to the Lachman test (before and after reconstruction) and the pivot-shift test (before reconstruction).

Study design

A total of 8 subjects with an ACL rupture in one knee, who are planned for hamstrings tendon reconstruction are included in the study. The subject should be older than 18 years and give informed consent. Antero-posterior and rotational laxity of the knee is determined using Lachman test, pivot-shift test, PKTD MRI scans and a 3D finite element model. Additionally, the ACL attachment sides are obtained before and after reconstruction. Before the reconstruction surgery both, healthy and injured, knees will be scanned and tested with the Lachman and pivot-shift test. Three months after the reconstruction, only the reconstructed knee will be scanned and tested using the Lachman test. The MR images will be used as input for the finite element model, after segmentation and meshing.

Study burden and risks

Subjects who participate in the study do not have any direct benefit of participation. The risk associated to the MRI scan, PKTD, or the other clinical tests are completely non-invasive and as such the health risk involved for participating subjects can be deemed negligible. The outcome of this study will inform researchers and clinicians of a new technology to improve future ACL reconstructions.

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

The subject should be 18 years old or older.
The subject should have an ACL rupture in one knee.
The subject should have a non-ACL deficient knee.
The subject should be able to read and understand the subject information.
The subject should be planned for a hamstrings tendon revision.

Exclusion criteria

The subject has a joint replacement implant.
The subject has lower limb arterial insufficiency.
The subject has venous diseases.
The subject has haemophilia.
The subject has known or suspected osteoporosis.
The subject has a bone disease with bone fragility.
The subject cannot articulate pain or discomfort.
The subject does not meet standard criteria for MRI scanning.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2015
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Porto Knee Testing Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL52734.018.15