Biomechanical analysis of anterolateral rotatory instability in anterior cruciate ligament reconstruction with or without lateral extra-articular tenodesis.

Published: 18-03-2016
Last updated: 19-04-2024

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

Summary

ID

NL-OMON46326

Source
ToetsingOnline

Brief title
BALET

Condition

- Tendon, ligament and cartilage disorders

Synonym
Anterior cruciate ligament, anterolateral rotatory instability

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie

Source(s) of monetary or material Support: Wetenschapsfonds;HMC;Den Haag

Intervention

Keyword: Anterior cruciate ligament, Anterolateral ligament, Lateral extra-articular tenodesis

Outcome measures

Primary outcome

To describe the anterior-posterior translation, internal-external rotation and medial-lateral translation as a function of flexion and knee state (intact contralateral control, ACL deficient, ACL reconstructed with LET, and ACL reconstructed without LET).

Secondary outcome

Patient related outcome measurements (PROMs) through validated questionnaires:

IKDC, KOOS, Tegner, anchor questions.

Study description

Background summary

Even the most recent anterior cruciate ligament (ACL) reconstruction techniques remain unable to fully restore normal knee joint biomechanics to normal. The key to restoring better knee kinematics in ACL surgery lies in understanding the structures that are damaged in addition to the ACL. Previous studies have shown that anterolateral extra-articular structures (ALES) may be injured during initial ACL injury of the knee. Failure to recognize and manage these concomitant injuries might result in persistent postoperative anterolateral rotatory instability of the knee, increased forces through the ACL graft and eventually lead to failure of the primary ACL reconstruction. Concomitant lateral extra-articular tenodesis (LET) to the ACL reconstruction might be able to restore the kinematics of the knee. However, no in vivo information on the combined ACL with LET exists.

Study objective

The specific aim of this research project is to measure the tibiofemoral kinematics during in vivo weight bearing lunges of patients at two time points: (1) prior to ACL reconstruction with or without LET, and (2) six months after ACL reconstruction with or without LET using a combined dual fluoroscopic and magnetic resonance (MR) imaging technique, with the healthy contralateral knee as control.

Study design

This study is a randomized clinical trial, consisting of 52 patients with 6 months follow-up. The ACL injured patients will be evenly randomized into two groups of 26 patients. One group will be reconstructed with the ACL reconstruction with LET and the other group of patients will be reconstructed with solely ACL reconstruction.

Patients will be tested two times through weight bearing lunges. *Test 1*, prior to the ACL reconstruction: MR imaging of both knees i.e. the injured and healthy contralateral knees, and dual fluoroscopic imaging of both the injured and healthy contralateral knees. *Test 2*, six months after ACL surgery with or without LET: dual fluoroscopic imaging of the operated knees, no additional MR imaging will be made.

Intervention

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Study burden and risks

For the purpose of this study one extra MR-scan will be made of the healthy contralateral knee (20min); two dual fluoroscopic imaging studies will be used to evaluate the tibiofemoral kinematics (30min/study). However, the total amount of radiation is within the acceptable health standards and is lower than the natural background radiation and the annual allowed radiation exposure. All patients whom have ACL surgery in our hospital are asked to fill out standardized questionnaires (IKDC, KOOS, Tegner, anchor questions). These questionnaires will be used to analyze the patient related outcome measures (PROMs).

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: 18-40 years
Acute ACL deficient knees (<6 months from injury)
Lachman test 3+ (i.e. > 10-mm translation) on clinical examination
Pivotshift test grade III on clinical examination (i.e. implying anterolateral extra-articular structures are insuffisient)
Scheduled for ACL surgery
Written informed consent

Exclusion criteria

Collateral ligaments injury that requires surgery
Evident cartilage lesions
Injury to underlying bone
Injury or prior surgery to the contralateral knee
Pregnant patients
Patients unable to have MR

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2017
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-04-2017
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-06-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	02-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54848.098.15
Other	nog niet bekend