Anterior cruciate ligament reconstruction versus anterior cruciate ligament + lateral extra-articular reconstruction

No registrations found.

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

Summary

ID

NL-OMON21585

Source
Nationaal Trial Register

Brief title
BALET

Health condition

Anterior cruciate ligament tear / reconstruction (ACL)
(Antero)lateral extra-articular injury / reconstruction / tenodesis (LET / EAT / LER)

Sponsors and support

Primary sponsor: Haaglanden Medical Center (HMC)
Source(s) of monetary or material Support: Haaglanden Medical Center Research Fund

Intervention

Outcome measures

Primary outcome

The primary objectives are 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

The secondary objectives are to determine the patient subjective outcomes using validated and reliable questionnaires (IKDC, KOOS, Tegner questionnaire and anchor questions).

Study description

Background summary

Rationale: 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) with the ACL reconstruction might be able to restore the kinematics of the knee. However, no in vivo information on the LET exists.

Objectives: To evaluate (1) the in vivo kinematics using a combined dual fluoroscopic imaging system and magnetic resonance imaging technique of patients who undergo ACL surgery with or without concomitant LET, with the healthy contralateral knee as control; (2) patient subjective outcomes using questionnaires (IKDC, KOOS and the Tegner questionnaires and anchor questions).

Hypothesis: Our null hypothesis is that there are no differences in tibiofemoral joint kinematics after ACL reconstruction with LET and the tibiofemoral joint kinematics after ACL reconstruction without LET. Our alternative hypothesis is that ACL reconstruction with LET more closely restores the tibiofemoral joint kinematics to normal (i.e. those of the healthy contralateral knees) compared with ACL reconstruction without LET.

Study design: Randomized clinical trial with 6 months follow-up.

Study population: 52 patients, 18-40 years old.

Main study parameters/endpoints: 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).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The LET is not new, and has been described since the ‘80s. The LET is no standard orthopedic care in all hospitals, but is indicated to perform in excessive anterolateral rotatory instability (i.e. Pivotshift grade III). The same experienced sports orthopedic surgeon will treat all patients. An additional MR scan of the contralateral knee will be made. Also, two observational tests in addition to the regular treatment protocol will be performed by means of a dual fluoroscopic technique, exposing the patient to additional, albeit minimal, Rontgen rays. Future patients will benefit from this study, as the optimal treatment for knee instability following ACL rupture will be determined.

Study objective

Our null hypothesis is that there are no differences in tibiofemoral joint kinematics after ACL reconstruction with LET and the tibiofemoral joint kinematics after ACL reconstruction without LET. Our alternative hypothesis is that ACL reconstruction with LET more closely restores the tibiofemoral joint kinematics to normal (i.e. those of the healthy contralateral knees) compared with ACL reconstruction without LET.

Study design

Time Frame:

T1: up to 4 weeks prior to surgery

T2: 6 months after surgery

Intervention

standard ACL reconstruction vs ACL reconstruction + LET

Contacts

Public
MCH Westeinde
Secretariaat Centrum voor Beweging A2-72
Postbus 432

Arkel, van
Den Haag 2501 CK
The Netherlands
Scientific
MCH Westeinde
Secretariaat Centrum voor Beweging A2-72
Postbus 432

Arkel, van
Den Haag 2501 CK
The Netherlands

Eligibility criteria

Inclusion criteria

- Age: 16-40 years

- Acute ACL deficient knees (<6 months from injury)

- Lachman test 3+ (i.e. > 10-mm translation) on clinical examination

- Pivotshift test grade II/III on clinical examination (i.e. implying anterolateral extra-articular structures are damaged)

- Scheduled for ACL surgery

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2017
Enrollment:	52
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2017
Application type:	First submission

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
NTR-new	NL6425
NTR-old	NTR6602
Other	METC : 16-004

Study results