

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

Gepubliceerd: 31-07-2017 Laatste bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21585

Bron

Nationaal Trial Register

Verkorte titel

BALET

Aandoening

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

Ondersteuning

Primaire sponsor: Haaglanden Medical Center (HMC)

Overige ondersteuning: Haaglanden Medical Center Research Fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Time Frame:

T1: up to 4 weeks prior to surgery

T2: 6 months after surgery

Onderzoeksproduct en/of interventie

standard ACL reconstruction vs ACL reconstruction + LET

Contactpersonen

Publiek

MCH Westeinde

Secretariaat Centrum voor Beweging A2-72

Postbus 432

Arkel, van
Den Haag 2501 CK
The Netherlands

Wetenschappelijk

MCH Westeinde

Secretariaat Centrum voor Beweging A2-72

Postbus 432

Arkel, van
Den Haag 2501 CK
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-07-2017
Aantal proefpersonen:	52
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	31-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6425

Register

NTR-old

Ander register

ID

NTR6602

METC : 16-004

Resultaten