Dynamic Computed Tomography for assessment of Knee Rotational Stability after Anterior Cruciate Ligament Injury

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24497

Source
Nationaal Trial Register

Brief title
DYCK

Health condition

Anterior cruciate ligament injury

Sponsors and support

Primary sponsor: Academic Hospital, ErasmusMC and IJsselland Hospital.
Source(s) of monetary or material Support: Academic hospital EMC

Intervention

Outcome measures

Primary outcome

Difference in rotational stability of the ACL deficient and normal knee in degrees

Secondary outcome

- The pivot-shift test (gold standard)
- Other physical examination tests (Lachman, KT2000, anterior drawer, posterior drawer, dial test)
- Clinical related outcome measures: IKDC 2000

Study description

Background summary

Rationale: Anterior cruciate ligament (ACL) injury is one of the most common serious knee injuries in the young athlete. The ACL provides stability of the knee in anterior-posterior direction as well as in rotation. There has been a lot of development in ACL reconstruction surgery techniques the past decade. The reconstruction of the ACL complies two main goals, namely: restoration of anterior to posterior stability and restoration of rotational stability. Restoration of anterior to posterior stability can be achieved by reconstruction surgery of the ACL, though it is not well known what influence the ACL reconstruction has on rotational stability of the knee. One of the reasons the ACL reconstruction fails is assumed to be persistent rotational instability of the knee after ACL reconstruction. Though, we cannot measure the rotational stability of the knee reliable for there is currently no reliable technique available. New generation CT scanners (dynamic-CT) make it possible to assess moving joints in a quantitative manner, as is already been shown in the wrist carpal joints. This technique might provide essential information of knee rotational stability before and in a later stage after ACL reconstruction and hereby, possibly prediction of patient satisfaction after ACL repair.
Objective: To assess the rotational stability of the knee using dynamic CT scanning.
Study design: A feasibility study / pilot study. It will be a cross-sectional design. There will be an internal control. A dynamic CT scan will be performed of the injured as well as the uninjured knee to assess the differences in rotations.
Study population: Patients planned for ACL reconstruction surgery, with a unilateral symptomatic ACL deficiency will be included, 18-50 years of age.
Intervention (if applicable): All participants will receive the same ‘ intervention’, one dynamic-CT scans of each knee, left and right, prior to ACL reconstruction.
Main study parameters/endpoints: Degrees of rotation (femur versus tibia) of the injured versus the uninjured knee.

Study objective

It is possible to measure knee rotational stability of ACL deficient compared to ACL intact knees using dynamic-CT.

Study design

One measurement after ACL rupture

Intervention

Dynamic CT of the knee

Contacts

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Eligibility criteria

Inclusion criteria

• Uni- lateral symptomatic knee instability and ACL deficiency.
• Planned for ACL reconstruction surgery
• Age between 18 – 50 years
• A written informed consent should have been signed

Exclusion criteria

• Symptomatic contra-lateral knee
• Prior injury to contra-lateral knee
• Pregnancy
• Patient is unwilling to participate
• Unable to speak, read and write in Dutch

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-10-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-08-2019
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	NL7981
Other	METC EMC : METC078

Study results