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

Published: 27-09-2019
Last updated: 12-04-2024

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

Summary

ID

NL-OMON55500

Source
ToetsingOnline

Brief title
Dynamic CT of the Knee (DYCK)

Condition

- Tendon, ligament and cartilage disorders

Synonym
Anterior cruciate ligament injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anterior Cruciate Ligament, CT, Instability, Knee

Outcome measures

Primary outcome

Rotational stability (femur versus tibia) of the injured versus the uninjured

knee.

Secondary outcome

Rotational stability of the knee measured by the pivotshift test compared to

rotational stability measured by dynamicCT

Study description

Background summary

Anterior cruciate ligament injury is one of the most common serious knee injuries in the young athlete. The anterior cruciate ligament (ACL) plays an essential role in knee function. It provides stability of the knee in anterior posterior direction as well as in rotation. If conservative treatment of an ACL injury fails or the patient has a very active lifestyle, ACL reconstruction surgery is the gold standard for treatment. 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.
The anterior to posterior stability of the knee can be assessed by physical examination by the Lachman test and the anterior drawer test and the KT1000 measurement tool. These test are straightforward and have moderate to good sensitivity and specificity if performed by an experienced orthopaedic surgeon. Though anterior to posterior stability can be measured in a straightforward manner. To measure rotational stability, only physical examination by the pivot shift test is available. The pivot shift test is a manually performed test, which has gradings from 03. When the patient is apprehensive, the test cannot be performed reliably. Furthermore there is a lot of interobserver variability. One of the reasons the ACL reconstruction fails is assumed to be persistent rotational instability of the knee after ACL reconstruction. Recent studies correlate residual rotatory instability with decreased patient satisfaction, increased functional instability, chondromalacia and the development of

osteoarthritis. The possible importance of knee rotational stability for patient satisfaction urges the need for an quantitative straightforward measuring tool for the assessment of rotational stability of the knee before and after intervention for ACL injury.
Recently CT scanners have improved a lot. Today it is possible to assess a beating heart by the use of CT. Scanning time and with this radiation exposure is decreased tremendously in newly developed machines. These new generation CT scanners also make it possible to assess moving joints as is already been shown in the wrist carpal joints and the patella femoral joint. The movement of translation and rotation of different bones can be obtained in a highly quantitative and reproductive manner. Though, recently it is proved that dynamic CT scanning can be performed on the patello0femoral and the wrist carpal joints. The movement of the tibia in relation to the femur and hereby assessment of rotational stability of the knee after ACL injury has never been shown.
The availability of a dynamic CTscanner in the IJsselland hospital provides the opportunity to assess rotational stability of the knee using this technique. This technique might provide essential information of knee dynamics before and in a later stage after ACL reconstruction and hereby, patient satisfaction.

Study objective

For this technique is new and has never been applied for assessment of knee stability, our first goal is to assess the normal rotational stability of the compared to the ACLinjured knee. Measuring knee rotational stability of ACL deficient compared to ACL intact knees using dynamicCT.
We will test the feasibility, and the ease of the technique.

Study design

A feasibility study / pilot study will be performed first. The arbitrary number of 10 subjects with symptomatic unilateral ACL deficiency will be included. A dynamic CT scan will be performed of the injured as well as the uninjured knee to assess the rotations of the femur versus the tibia.
It will be a crosssectional study.

Study burden and risks

The participants will be informed about this study by the principle investigator.
The patients will have one additional visit to the hospital for dynamicCT scanning of the knees. This visit will take approximately 45 minutes. The dynamicCT scan of the knees will give a dose of approximately 0.6 mSv in total.
This is a low dosage, as in contrast; a normal CT scan of the hip is 3 mSv and the thorax is 18 mSv. The yearly exposure to radiation from natural sources is

about 2 mSv.
There is no individual benefit for the participant, though the results might in future predict the patient satisfaction after an intervention, and might change interventional strategies.

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

Anterior cruciate ligament injury
Contralateral normal knee
Symptomatic knee instability
Planned for anterior cruciate ligament reconstruction

Exclusion criteria

Pregnancy
Unwilling to participate
(old) injury of the not affected knee

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-10-2019
Enrollment:	0
Type:	Anticipated

Ethics review

Approved WMO Date:	27-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL67874.078.18