Validity study of diagnostic test of the anterior cruciate ligament.

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

Summary

ID

NL-OMON34642

Source
ToetsingOnline

Brief title
Accuracy diagnosis ACL rupture

Condition

- Tendon, ligament and cartilage disorders

Synonym
", "anterior cruciate ligament rupture"

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: ACL rupture, arthroscopy, reproducibility, validity

Outcome measures

Primary outcome

Sensitivity, specificity, likelihood ratios and predictive values of a positive and negative test result are calculated for the following clinical tests: The Lachman test, the pivot shift and the anterior drawer. All subjects already underwent arthroscopic surgery which obtains the reference test.

Secondary outcome

Secondary this study assessed the intertester reliability and the value of the medical history in the diagnostic process.

Study description

Background summary

Study results regarding the accuracy of clinical tests for assessing anterior cruciate ligament ruptures gives us heterogeneous data. Reviewing the literature, as in the meta-analysis of Benjaminse et al. (2006) shows the shortcomings in methodological quality in most of the current data of these studies. Especially the lack of using a valid control group and a valid reference test is remarkable.

Study objective

The objective of this study is to define the accuracy and the inter observer reliability of the clinical tests for assessing anterior cruciate ligament ruptures. These tests compose the standard in clinical testing for diagnosing or monitoring the traumatic knee.

Study design

Subjects in this study are asked to visit the out-patient clinic of the Erasmus MC. A curtain will be used to screen the subject*s upper body and face from the

examiner*s view and to reduce the chance of recognition. The tests will be administered by an orthopaedic surgeon and a general practitioner. Both will fulfil the tests without any knowledge of the subject*s medical history. After finishing these first tests, graded and noted the results, they are allowed to read the subject*s standardized medical history. After this moment they will re-test the subject with the same clinical tests. They are asked to decide whether both test moments and the medical history match with a diagnosis of an anterior cruciate ligament rupture.

Study burden and risks

Estimated burden for participating in the clinical tests and the KT-100 arthrometer test is approximately 1 hour. Regarding the inclusion and exclusion criteria there is no additional risk in participating in this study.

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

Visit of outpatient clinic because of tarumatic knee complaints and arthroscopy in the period January 2008 till March 2010.
Minimal age of 18 year.
- free range of motion, no effusion and no knee pain which will influence the physical examination.
-Contralateral knee with a free history.

Exclusion criteria

-Presence of hydrops/ haemarthros in one of both knees, which will influence the termination of physical examination
-An extension deficit of minimally 10° in one of both knees;
-A maximal flexion of 100° or less in one of both knees;
-A history of fracture of the tibia or femur;
-A anterior cruciate ligament reconstruction;
-Knee pain of one of both knees which will influence the termination of physical examination
-A not traumatic rupture of the anterior cruciate ligament rupture

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2010
Application type:	First submission
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	NL31949.078.10