Validation of a method to measure proprioception in ACL deficient knees

Published: 09-01-2009
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Objective: Validation of proprioception measurement device in ACL deficient patients.

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

Summary

ID

NL-OMON30872

Source
ToetsingOnline

Brief title
Validation ProSys / HINKLE-4

Condition

- Tendon, ligament and cartilage disorders

Synonym
Anterior cruciate ligament deficiency

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ACL, knee, proprioception, threshold

Outcome measures

Primary outcome

Main study parameters/endpoints: Threshold to detect passive motion (TTDPM)

with a special designed apparatus will be measured in different motions and

start positions of the knee. Results of the index group will be compared to

existing results of control group.

Secondary outcome

not applicable

Study description

Background summary

Rationale: According to several studies patients with an anterior cruciate ligament (ACL) lesion have a lowered proprioceptive ability in the injured knee. The threshold to detect passive motion (TTDPM) in the knee is regarded as an indication of the quality of proprioception; a higher threshold suggests a lowered proprioception. At Lund University Sweden an apparatus has been developed to measure the TTDPM. In 2006 a new apparatus based on the Lund device has been developed in the UMCG. The reliability and validity of this apparatus in healthy subjects have been tested and have been proofed worthwhile.

Study objective

Objective: Validation of proprioception measurement device in ACL deficient patients.

Study design

Study design: Case-control study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Non-therapeutic and non-invasive study with

negligible risks and minimal burden. As the main parameter has only been described in ACL deficient patients, this study can only be done using these patients. Patients will get questionnaires and physical examination (IKDC form). They will perform one test with 4 sessions (average total duration 60 minutes).

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
- Conservative treatment
- waiting for ACL reconstruction
- 18 years or older

- unilateral disease

Exclusion criteria

- younger than 18 years
- neuromuscular disorder
- injury of contralateral knee

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL17985.042.07