Knee Rehabilitation on Skates

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The main study objective will be to determine whether a newly developed rehabilitation protocol is non-inferior to the current rehabilitation protocol - golden standard - used after ACL reconstruction.

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

Summary

ID

NL-OMON45964

Source
ToetsingOnline

Brief title
KROS

Condition

- Tendon, ligament and cartilage disorders

Synonym
ACLinjury

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: Anterior Cruciate Ligament Reconstruction, Ice skating, Rehabilitation

Outcome measures

Primary outcome

Is our newly developed rehabilitation protocol KROS non-inferior to standard care.

Definition of inferiority: Unable to reach a functional Limb Symmetry Index of 81%, 9 months after ACLR which corresponds to 90% of standard care.

Secondary outcome

Time to reach a functional limb symmetry index of 80% (end of phase 2)

Time return to play defined as a functional limb symmetry index of 90% (end of phase 3)

Hamstrings and Quadriceps strength

Quadriceps/Hamstrings ratio

Rate of re-rupture of the ACL graft

Adverse events

Study description

Background summary

Return to play after anterior cruciate ligament (ACL) reconstruction is one of the main goals of surgery. On average it takes up to nine months after surgery to return to play. A long period of the field could be frustrating for young athletic individuals. On top of that, reviews have shown that a mere 55 per cent of patients after ACL reconstruction can return to their pre-injury level of sports. Also, up to 25% of re-rupture rate has been reported after ACL reconstruction.
In order to improve these outcomes after ACL reconstruction a new rehabilitation protocol has been developed. This rehabilitation protocol focuses on balance, core stability and strength and might be able to speed up

the rehabilitation process, improve the rate of return to pre-injury level of sport and decrease the amount of re-ruptures after ACL reconstruction. In addition, the newly developed protocol may be more attractive for participants, which may lead to better compliance

Study objective

The main study objective will be to determine whether a newly developed rehabilitation protocol is non-inferior to the current rehabilitation protocol - golden standard - used after ACL reconstruction.

Study design

non-randomized , controlled, non-inferiority , multicentre trial

Intervention

KROS rehabilitation protocol, see chapter 3.1

Study burden and risks

A structured risk analysis has been carried out. This analysis led to the conclusion that a negligible risk is accepted.

The KROS rehabilitation protocol replaces the gold standard and is comparable in intensity, i.e. training twice a week under the supervision of a physiotherapist. The content of the training will differ. The measuring moments are carried out during the training sessions, which will take about 15 minutes extra per measuring moment. In total there are four measuring moments. Emotional stress is kept to a minimum by on the one hand the non-randomized nature of the study and on the other hand by the continuous presence of a physiotherapist during the skating training.

The risk of falls and major balance disturbances is minimized by proper preparation and setting requirements that a subject must meet before the skating training starts.

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

- > 18 years
- ACL deficiency requiring ACL reconstruction
- Intact contralateral knee on physical examination
- written informed consent

Exclusion criteria

- Additional surgical procedures altering postoperative rehabilitation protocol (e.g. meniscal repair)
- Patients with any history of fractures in the lower extremities or spine
- Previous musculoskeletal surgery in the lower extremities
- Neurological conditions leading to musculoskeletal disorders
- Inability to complete Dutch questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	27-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-08-2019
Application type:	Amendment
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	NL66171.042.18