The effects of cross-education on loss of muscle strength and knee function after ACL reconstruction

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Primary Objective:The aim is to compare the effects of rehab with standard care vs. standard care plus XED on loss of muscle strength and function in the operated limb at the end of phase I rehab after ACL reconstruction surgery.

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

Summary

ID

NL-OMON39793

Source
ToetsingOnline

Brief title
Cross-Education After ACL Reconstruction

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym
anterior cruciate ligament rupture, anterior cruciate ligament tear

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 reconstruction, cross-education, knee function, muscle strength

Outcome measures

Primary outcome

a) Return to sport or work status at 6 months, b) Cincinnati Knee Score a test that is valid and sensitive to measure changes over time in patients* knee status after ACL rehabilitation, c) Pain intensity (0 to 100) (23) and global knee function (0 to 100).

Secondary outcome

a) hop test, b) balance, c) proprioception, d) force control, e) maximal force and power, and f) gait variability.

Study description

Background summary

There is over 30% loss of voluntary muscle force in the operated leg after an anterior cruciate ligament (ACL) reconstruction surgery. Patients could return to sport or work sooner by minimizing muscle weakness. Imaging, brain stimulation, and behavioural studies show that exercise a muscle in one limb improves function of the same muscle in the other, non-exercised limb. The possibility exists that XED can reduce strength and functional losses and help ACL-reconstructed patients recover faster.

Study objective

Primary Objective:
The aim is to compare the effects of rehab with standard care vs. standard care plus XED on loss of muscle strength and function in the operated limb at the end of phase I rehab after ACL reconstruction surgery.

Study design

This study will be a randomized clinical trial with two arms: standard care and

standard care plus XED. The standard care plus XED group will receive standard care plus structured exercise training of the non-operated quadriceps muscle. Measurements: 1) 1 week before surgery, 2) End of Phase I rehab at 4 weeks, and 3) 3 months after surgery 4) Minimum follow-up of 6 months follow. Primary outcomes: a) Return to sport or work status at 6 months and b) Cincinnati Knee Score. Secondary outcomes: hop test, balance, proprioception, force control, maximal quadriceps torque, and gait quality.

Intervention

The control group will receive standard care of ACL rehab and the other group will receive standard care plus extra exercise training of the non-operated leg.

Study burden and risks

The clinical tests are part of the standard patient care and require no extra time or effort. Patients visit the Center for Human Movement Sciences one time before ACL reconstruction surgery, one time 4 weeks after surgery, and for a 3rd and final time 6 months after surgery for about 1.5 hours. The laboratory tests will measure each quadriceps muscle*s ability to produce and control force in a standardized way. The force control task requires minimal effort to aim at a target at a low force and match the target force as accurately and steadily as possible. The maximal knee extension task is also a standard test and consists of ~2-s-long efforts with 1-2 min of rest between contractions. Muscle activation is measured during the quadriceps test by electrically stimulating the quadriceps muscle through the skin. This peripheral nerve stimulation causes the muscle to twitch, this can be more surprising than painful. It can cause some momentary burning and tingling sensation. The balance test requires the patient to hold his/her balance on a board. The proprioception test measures the ability to sense the position of the leg unloaded and requires minimal effort. Gait variability is measured during slow walking on a treadmill and is a sensitive test of symmetry and neural control of gait. Electromyography (EMG) of the quadriceps will be recorded. Therefore the skin underneath the three electrodes will be shaved and cleaned. This may cause some light irritation of the skin. There will be minutes of rest between each test.

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

Patients awaiting an ACL reconstruction surgery will be included: male, female, age 20 to 60, any race, BMI<30 kg/m2, ACL tear to the dominant or non-dominant leg with or without meniscal excision, hamstring autograft, allograft of any source, signed informed consent, and follow study protocol.

Exclusion criteria

if they are pregnant (surgeon will look in the medical record of the patient), have an injury to the other leg, a meniscal tear requiring repair, additional interventions that interfere with standard rehab (e.g., cartilage lesion treatment), multiple serious injuries to target leg (ACL tear+meniscus tear, ACL+plus collateral ligament tear, prior major surgery to legs, pelvis), revision ACL reconstruction on the same knee, degenerative arthritis on radiographs or articular cartilage fissures extending to subchondral bone, or exposed bone as seen in arthroscopy (grade IV), current or prior neurological conditions (Parkinson*s disease, stroke, dementia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	20-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	22-01-2014
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	NL42600.042.12