

Surgical Management of Deep Posterior Compartment Syndrome of the Leg

Published: 15-02-2008

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Compare two surgical techniques for treatment of posterior CECS.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31782

Source

ToetsingOnline

Brief title

Surgery of CECS of the leg

Condition

- Soft tissue therapeutic procedures

Synonym

Chronic Exercise Induced Compartment Syndrome, Compartment Syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CECS, deep posterior, leg, surgery

Outcome measures

Primary outcome

The change in intracompartmental pressure measured by the dynamic pressure measurement pre- and post-operatively.

Secondary outcome

The secondary study parameter is the change in pain in daily/sports activities expressed by a VAS score.

Study description

Background summary

Surgery for a Chronic Exercise Induced Compartment Syndrome (CECS) of the posterior muscles of the leg has poor post-operative results. Different surgical techniques have been proposed but none has shown to be superior.

Study objective

Compare two surgical techniques for treatment of posterior CECS.

Study design

Randomised Controlled Trial

Intervention

Group 1: release of the fascia cruris

Group 2: release of the fascia cruris, as well as a release of the m. flexor digitorum, while leaving the insertion in place. Inspection of the m. tibialis posterior for an eventual extra compartment, and eventual release.

Study burden and risks

The main risk is that the group treated with the limited fasciotomy may be under treated.

An additional risk is that the patients will have to undergo an extra intra-compartmental pressure measurement post-operatively. Nevertheless, these

measurements are usually not associated with substantial health risks.
Other burdens will be an extra visit to the hospital for an MRI-scan
pre-operatively and questionnaires to be filled out.

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

- individuals (m/f) suffering from CECS
- a positive dynamic compartment pressure measurement
- 18-40 years, since it s a sports-related injury and this is the predominant age group where CECS occurs
- sports-related
- just the deep posterior compartment involved. This can be determined by the pressure measurement

- failure of conservative management (physical therapy/inlays)

Exclusion criteria

Previous surgery on the leg

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO	
Date:	15-02-2008
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL18179.015.07