Fasciotomy as treatment of Chronic exertional compartment syndrome of the deep posterior compartment - a prospective study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON37159

Source
ToetsingOnline

Brief title
CECS-Fas

Condition

- Muscle disorders

Synonym
Chronic compartment syndrome, exertional compartment syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Isala klinieken

Intervention

Keyword: Chronic compartment syndrome, Deep posterior compartment, Exertional compartment syndrome, Fasciotomy

Outcome measures

Primary outcome

Meassurement of Intracompartimental pressure of the deep posterior compartment

will be repeated six weeks after surgery and will be compaired with the

readings before surgery

Secondary outcome

VAS-score for pain, Rand-36, Van Zoest 2008 questionnairy before surgery and 6

weeks after. Likert score for recovery 6 weeks after surgery.

Study description

Background summary

Chronic exertional compartment syndrome is charecterised by pain and loss of function. The symptoms occur due to tightness of the conective tissue surrounding the muscles or due to hyperthropy of the muscles within the conective tissue. Chronic exertional compartment syndrome of the anterior compartment leads to typical complaints and has a good correlation between the complaints and the affected muscles in the afflicted compartment. The exertional compartment syndrome of the deep posterior compartment has a less typical complaintspattern. It is therefor less easily recognisable. The location between the fibula, the tibia and the other compartments gives rise to the theory that a fasciotomy gives less pressure relieve for the afflicted compartment.

Study objective

This study aimes to investigate wheter or not a fasciotomy of the deep posterior compartment of the lower leg leads to a lowering of the intracompartimental pressure, an objective parameter. . This study will also

investigate wheter or not a fasciotomy leads to a subjective improvements of complaints. The primary goal of this investigation is to determine if a fasciotomy of the deep posterior compartment leads to a decrease in pressure in that same compartment. The secundary goal of this investigation is to determine whether or not a fasciotomy of the deep posterior compartment of the lower leg leads an improvenmtent of pain and quality of life.

Study design

This study is a prospective study. There will be no randomisation. Patients with elevated pressures in the deep posterior compartment are allegeble and will be approached to participate in the study. Questionnairies will be taken before and after surgery. Six weeks after surgery intracompartimental pressure readings will be repeated.

Study burden and risks

Filling in of the questionnaires should take no more then 30 minutes. The intracompartmental pressure measurement is repeated six weeks after surgery. This measurement takes approx. 45 minutes.

Intracompartmental pressure measurement is performed as follows: the skin is desinfected and locally anesthetized. A slit-catheter is placed in the deep posterior comparment and fixated. Pressure measurements are then performed in sitting and upright position pre-exercise, during exercise and in sitting and upright position after the patient has exercised.

Contacts

Public
Isala Klinieken

Groot Wezenland 20
Zwolle 8011 JW
NL
Scientific
Isala Klinieken

Groot Wezenland 20
Zwolle 8011 JW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elevated intracompartimental pressure in deep posterior compartment
(resting pressure >20 mmHg or 1 minute after exercise >25 mmHg or 5 minutes after exercise >20 mmHg)

Exclusion criteria

- Proven compartment syndrome of any compartment of the lower leg other than the deep posterior compartment
- Tibial or fibular stress fracture
- Medial tibial stresssyndrome
- Surgery on the lower leg or ankle in the last 12 months
- Acute Lower back symptoms
- Periferal vasculalr disease
- Diabetes Mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	22
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-12-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL41172.075.12