Comparison between two surgical methods in the treatment of anterior chronic compartment syndrome: a patient blinded, randomized study.

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To compare two surgical techniques in the treatment of patients with a anterior CECS.Surgical method 1: use of conventional *Due* fasciotome Surgical method 2: use of the new *Fasciomax©* in stead of the *Due*-fasciotome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON44856

Source
ToetsingOnline

Brief title
Comparison two surgical methods in the treatment of anterior CECS

Condition

- Connective tissue disorders (excl congenital)

Synonym
anterior chronic compartment syndrome, CECS (chronic exertional compartment syndrome)

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Het onderzoek wordt gefinancierd door RVE stichting Maxima Medisch Centrum. Eindverantwoordelijk voor financiering is de maatschap Chirurgie van het MMC Veldhoven

Intervention

Keyword: CECS, comparison, surgery, treatment

Outcome measures

Primary outcome

Primary outcome of the study is post-operative pain in the entry site and the leg in general, which patients will note on a daily basis for 2 weeks after surgery using a 11-point Numerical rating scale. This will be done for both separate legs. Furthermore, patients will note pain medication. Both will be collected in a questionnaire.

Secondary outcome

Efficacy (3 months after surgery) and the occurrence of complications.

Efficacy will be determined by assessing complaint reduction using questionaires (pre-operative and 3 months post operative). Patients will denote their complaints (pain, cramps, muscle weakness, tight feeling, sensibility disorders) using a 5-point Verbal Rating Scale

Complications will be assessed by the responsible physician 2 weeks after surgery.

Study description

Background summary

In some patients chronic lower leg pain is caused by a chronic exertional compartment syndrome (CECS) which is characterized by high pressure in muscle

compartments. In most patients with CECS, pain is caused by high pressure in the anterior compartment which contains the anterior tibial muscle. When diagnosed via pressure measurement, surgical treatment is initiated. Due to the lack of evidence for conservative treatment the current gold standard for treating CECS is to surgically split the tight fascia surrounding the muscle. Thereby the increased pressure in the compartment is abolished and the pain is relieved. Splitting the fascia is performed using a fasciotome. In the Maxima Medical Center a Due fasciotome is used. Acoording to own patientdata and literature concerning prospective studies the succesrate after a fasciotomy using the 'Due' fasciotome is on average 83%. An avoidable cause is suboptimal execution of the fasciotomy. A half-closed fasciotomy, according to 'Due' has potential riks and complications: 1. the unprotected mouth could rupture bloodvessels causing bleeding and hematoma's; 2. by executing the fasciotomy 'blinded', nerves that are located next to the fascia can be damaged, resulting in sensory disorders; 3. uncomplete splitting when the fasciotome losed contact with the fascia; some patients have multiple fascia's that overlap. When using the 'Due' fasciotome only one fascia is split.

Recently, a new surgical tool has been designed in the Maxima Medical center to use during the procedure: the Fasciomax©. This fasciotome consists of a long mouth that is able to enclose the entire fascia prior to cleaving it. Thereby there is reduced chance of damaging vessels or nerves and incomplete cleaving.

Study objective

To compare two surgical techniques in the treatment of patients with a anterior CECS.

Surgical method 1: use of conventional *Due* fasciotome
Surgical method 2: use of the new *Fasciomax©* in stead of the *Due*-fasciotome.

Study design

Single centre, single surgeon, patient-blinded randomized clinical trail.

Intervention

Included patients with double-sided CECS will undergo surgery with the Due fasciotome in one lower leg, while in the other lower leg the Fasciomax© will be used. The allocation of the intervention to either the right leg of left leg is randomized. Save the use of a different fasciotome the procedure and care for both legs is exactly equal.

Study burden and risks

It is expected that participation to this study will not induced additional risks for the participants. However, participants are burdened with a extensive questionaire (2 times), and denoting daily pain scores the first 2 weeks following surgery.
Potential benefits are a reduction of post-operative pain and a reduced risk for complications.

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

- Male and female patients who are older than 18 years
- Chronic anterior compartment syndrome proven by clinical history, physical examination and pressure measurement
- Only the anterior lower leg compartment is affected, no combined compartment syndrome

including lateral of posterior compartment involvement.
- Patients have comparable complaints in both lower legs
- Patients have given informed consent.

Exclusion criteria

- Previous lower leg surgery
- Previous traumatic lower leg bone fracture
- Patients do not speak/underrstand Dutch

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:	Recruitment stopped
Start date (anticipated):	01-10-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Fasciomax
Registration:	No

Ethics review

Approved WMO

Date:	05-09-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-11-2017
Application type:	Amendment
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

ID: 23754
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44917.015.13
OMON	NL-OMON23754