Comparison two surgical methods in the treatment of anterior CECS

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23754

Source
Nationaal Trial Register

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

Health condition

CECS
treatment
surgery
comparison

Sponsors and support

Primary sponsor: Maxima Medical Center
Source(s) of monetary or material Support: none

Intervention

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

N/A

Study objective

N/A

Study design

primary outcome. operation --> 2 weeks
Secondary outcome:
complications: 2 weeks post-operative
Efficacy: 3 months post-operative

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.

Contacts

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Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-09-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-11-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44856
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4072

Register	ID
NTR-old	NTR4274
CCMO	NL44917.015.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44856

Study results

Summary results

N/A