Validation of CPM#1 compressibility in healthy volunteers in rest and after exercise

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The primary objective is - To clinically validate the inter-observer reliability of compressibility measurements with the CPM#1 device during rest in healthy volunteers.

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

Summary

ID

NL-OMON56011

Source
ToetsingOnline

Brief title
Non-invasive measurement of compartment pressure: Reliability

Condition

- Muscle disorders

Synonym
Chronic Exertional Compartment Syndrom, Lower Leg Pain

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: CPM Sport AG

Intervention

Keyword: CECS, Comrpessibility, Non-invasive, Reliability

Outcome measures

Primary outcome

Inter-observer reliability of the compressibility measured with CPM#1 device

Secondary outcome

- To clinically validate the intra-observer reliability of compressibility

measurements with the CPM#1 device during rest in healthy volunteers.

- To investigate the effect of exercise on compressibility immediately, one

minute, and five minutes after exercise in healthy volunteers.

Study description

Background summary

Chronic Exertional Compartment Syndrome (CECS) is one of the exercise-induced lower leg pathologies. Recognition by patients and physicians is not optimal. As a consequence, many patients are undiagnosed and are forced to stop their sporting activities. To diagnose CECS, a doctor should be alerted by a patient*s history and a physical examination. If both suggestive of CECS, an invasive intra compartmental pressure measurement (ICPM) in the affected compartment may be performed. During the ICPM a catheter is placed into the muscle via a hollow needle. The ICPM is not flawless in terms of accuracy and reproducibility and has a low intra-observer reproducibility. Moreover, haematoma or other tissue damage may occur following an ICPM. Nevertheless, this invasive ICPM is in 2022 still considered the *gold-standard* diagnostic tool for CECS, in the absence of a better one.
A novel non-invasive tool for CECS is possibly provided by measuring muscle tissue compressibility. The idea is, that muscle tissue with a high pressure (as in CECS patients) requires more external force to compress, compared to tissue with a low pressure. The study device used in this study, the CPM#1 device, is based on this principle. The CPM#1 device is non-invasive, not painful, very user friendly, and the measurement can be executed as an *office procedure* in a couple of minutes. This study will focus on determining the reliability of the device in healthy volunteers. The optimal way to perform

these measurements are however not standardized. Overall there have been two measurement methods reported to determine the compartment length. One orients the measurement towards the interosseous membrane between the tibia and fibula ('interosseous'), the other oerients at the intersection of the interosseous membrane to the tibia ('notch'). The orientation which has been used mostly in recent literature for the ultrasound measurements is the notch.

Study objective

The primary objective is
- To clinically validate the inter-observer reliability of compressibility measurements with the CPM#1 device during rest in healthy volunteers.

Study design

This study is a clinical performance validation pilot with the CPM#1 device that is tested in healthy volunteers. There will only be one study arm, no comparator, and no randomization. A second session will be implemented to also study the orientation towards the interosseous membrane after exercise, as preliminary analyses showed a higher than expected difference between the two orientations.

Study burden and risks

Healthy subjects will undergo several compressibility measurements, both before and after a treadmill exercise. They will also complete a NIAPS (Netwerk Inspannings Afhankelijke PijnSyndromen) questionnaire and an *experience* questionnaire. The harm associated with the CPM#1 device is none. However, the subjects will not benefit from this study.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500MB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- >= 18 years
- Proficient in speaking and reading Dutch

Exclusion criteria

- Presence or history of CECS
- History of surgery or other trauma which penetrated the fascia of the leg
- Other concurrent limb pathologies or anomalies amongst others:
- Peripheral arterial or venous disease
- Muscle disorders, diabetes mellitus, peripheral neuropathies
- Unable to exercise for 5-minutes
- Open wound at site of measurement

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-02-2023
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Compremium Compartmental Compressibility Monitoring System
Registration:	No

Ethics review

Approved WMO Date:	29-11-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-12-2023
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

No registrations found.

In other registers

Register	ID
CCMO	NL82601.015.22