Effects of high-frequency neuromuscular electrostimulation with external weights in patients with chronic obstructive pulmonary disease with severe symptoms of shortness of breath and dysfunction of lower extremity muscles: a pilot effects study.

No registrations found.

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

Summary

ID

NL-OMON23296

Source
Nationaal Trial Register

Health condition

chronic obstructive pulmonary disease (COPD)
neuromuscular electrostimulation (NMES)
external weights
intensity

chronisch obstructief longlijden (COPD)
neuromusculaire electrostimulatie (NME S)
externe gewichten
intensiteit

Sponsors and support

Primary sponsor: CIRO Horn
Source(s) of monetary or material Support: CIRO Horn

Intervention

Outcome measures

Primary outcome

The primary research parameter is to determine whe ther external weights affect NMES intensity (height mA), in patients with COPD characterized by muscle weakness and / or severe shortness of breath.

Secondary outcome

The secondary research parameters are the metabolic processes and m uscle activity of the bone muscularity in COPD patients.

The metabolic processes give an adequate picture of the patient's loadability. Muscle activity shows well the effects on muscle fiber levels.

Study description

Background summary

Patients with chronic obstructive pulmonary disease (COPD) still have symptoms of shortness of breath and fatigue in daily functioning despite optimal drug treatment. Pulmonary rehabilitation can improve these complaints. Unfortunately, not every COPD patient is able to complete the conventional training, due to effort-related dyspnea. Transcutaneous neuromuscular electrostimulation (NMES) is a relatively new treatment modality in patients with COPD with good results on skeletal muscle function, exercise tolerance and quality of life. To date, a high frequency has been used without external weights. There are indications that NMES with external weights can ensure that the intensity is increased during the intervention. The aim of this study is to determine whether external weights actually influence the intensity of NMES and the possible consequences on metabolic processes and muscle activity in patients with COPD.

Study objective

- The intensity is higher at NMES with external weights than at NMES without external weights, measured by reading the number of mA on the NMES device.

- The metabolic response is the same or higher during NMES in combination with external weights compared to NMES without the addition of weights due to a higher intensity, measured by reading the number of mA on the NMES device and a mobile oxycon.

- Muscle activation is higher during NMES in combination with external weights compared to NMES without the addition of weights due to a higher intensity, measured by reading the number of mA on the NMES device and an EMG measurement.

Study design

NMES will be applied to the patient with and without the addition of external weights, these external weights will be attached to the ankles. This will be carried out without weight and with 2.5 kg and once with 5.0 kg. The musculature is stimulated with a frequency of 75 Hz and a pulse duration of 400 microseconds. The intensity is increased by the patient to the tolerance limit. Patients are verbally motivated to increase the intensity as much as possible. When this is achieved, both metabolic processes and muscle activation will be assessed. The metabolic processes are maintained by means of a mobile oxycon. The muscle activity will be monitored by means of an EMG measurement

In total there are 3 measurement moments of 3 minutes per test. In the meantime there will be a moment of rest of 9 minutes (33). In total, the entire study will take about 45 minutes per patient.

Intervention

NMES will be applied to the p atient without the addition of external weights. The muscles are stimulated with a frequency of 75 Herz
and a pulse duration of 400 microseconds. The intensity is increased by the patient to the tolerance limit. Patients are verbally
motivated to increase the intensity as much as possible. During the NMES, metabolic load and muscle activation are measured. The
metabolic load is measured by means of a mobile oxycon. The muscle activity will be monitored by means of an EMG
measurement. These measurements will be measured both at the start and at the end of the treatment. During the tests it is necessary that the intervention is still ongoing.

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Eligibility criteria

Inclusion criteria

Patients with COPD

Medical Research C ouncil dyspnea scale (mMRC) 3/4

Muscle weakness of the lower extremities

Permission for voluntary participation

Being able to communicate in Dutch.

Exclusion criteria

Neuromuscular disorders

Known joint disorders in h ip, leg and / or knee

Metal implants in hip, leg and / or knee

Cardiac Pacemaker or Internal Cardiac Defibrillator (ICD)

Lack of motivation to voluntarily participate in this study

Patients requiring chronic oxygen therapy are excluded for the measurements to determine the metabolic
response

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-05-2018
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46386
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7031

Register	ID
NTR-old	NTR7236
CCMO	NL63531.100.17
OMON	NL-OMON46386

Study results

Summary results

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