The metabolic response during low-frequent and high-frequent neuromuscular electrical stimulation of the quadriceps muscles in patients with chronic obstructive pulmonary disease

Published: 04-05-2009
Last updated: 15-05-2024

Comparing the metabolic response (oxygenuptake and ventilation) and symptom perception (borgscores for dyspnoea and fatigue) between neuromuscular electrical stimulation with low-frequency and high-frequency.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON33670

Source
ToetsingOnline

Brief title
The metabolic response during NMES in patients with COPD

Condition

- Respiratory disorders NEC

Synonym
Chronic Obstructive Pulmonary Disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic obstructive pulmonary disease, metabolic response, neuromuscular electrical stimulation

Outcome measures

Primary outcome

Metabolic response:

- Oxygen uptake (VO2)

- Ventilation (VE)

Secondary outcome

Symptom perception:

- Borgscores for dyspnoea before and after the electrical stimulation

- Borgscores for fatigue of the leg muscles before and after the electrical

stimulation

Study description

Background summary

Patients with chronic obstructive pulmonary disease (COPD) still suffer from disabling dyspnoea, fatigue and exercise intolerance in daily life despite optimal drug treatment. Unfortunately, not every COPD patient is able to complete conventional training methods, due to exercise-induced dyspnoea. Transcutaneous neuromuscular electrical stimulation (NMES) is a relative new treatment modality, which has been shown to have positive effects on skeletal muscle function, exercise tolerance and disease-specific health status in patients with COPD.

Study objective

Comparing the metabolic response (oxygenuptake and ventilation) and symptom perception (borgscores for dyspnoea and fatigue) between neuromuscular electrical stimulation with low-frequency and high-frequency.

Study design

A prospective cross-over intervention study design.

Intervention

Neuromuscular electrical stimulation

Study burden and risks

The current research group believes that the nature and possible extent of the burden and risks possibly related to the present protocol are nihil and acceptable. Neuromuscular electrical stimulation had been used in previous studies (Neder et al, Thorax 2002; Bourjeily-Habr, Thorax 2002) and in daily routine without any adverse events.

The mobile oxycon had been used in previous studies in healthy subjects and patients with moderate to very severe COPD during exercise tests (for example: Probst et al, Chest 2004) and during extensive rehabolitation sessions (Probste et al, CERJ 2006) without any adverse events.

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

Chronic Obstructive Pulmonary Disease (COPD)
High rate of dyspnoea (MRC 4/5)
Normal or underweigth (BMI<25 kg/m2)

Exclusion criteria

Long-term oxygen therapy
Pacemaker or Internal Cardiac Defibrillator
Metal implants in hip, leg and/or knee
Neurological and/or locomotorical problems

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	11-05-2009
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	portable electrical stimulator en oxycon mobile
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-05-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 28216
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL25877.068.08
OMON	NL-OMON28216