Effects of 8 weeks lower-limb resistance training or lower-limb neuromuscular electrical stimulation (NMES) in severely dyspnoeic patients with chronic obstructive pulmonary disease (COPD) with lower-limb muscle dysfunction: a prospective single-blindrandomized controlled trial.

Published: 31-03-2010
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The purposes of this study are to study the effects of low-frequency NMES, high-frequency NMES and resistance training on health status, exercise tolerance and muscle strength in patients with COPD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON34655

Source
ToetsingOnline

Brief title
Effects of lower-limb resistance training or lower-limb NMES in COPD.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Chronic Obstructive Pulmonary Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Opdrachtgever is UM;Stichting Weijerhorst financiert het onderzoek.

Intervention

Keyword: COPD, neuromuscular electrical stimulation, resistance training

Outcome measures

Primary outcome

Maximum muscle strength of the leg muscles (expressed in Newton), measured with

the Biodex.

Secondary outcome

- Quadriceps muscle strength

- Exercise tolerance

- Body composition

- MRC dyspnoe grade

- Lungfunction

- Quality of Life (St. George's Respiratory Questionnaire)

- Adverse events (inclusive acute COPD exacerbations)

- Number of drop-outs

- Total level of daily physical activity (using a validated accelerometer)

- Oxygen uptake and ventilation

- Compliance rate

- Changes in vastus lateralis fibre type shift, fibre cross sectional area and

aerobic enzyme activity.

Study description

Background summary

Patients with Chronic Obstructive Pulmonary Disease (COPD) experience dyspnoea and fatigue durig daily physical activity, in spite of an optimal pharmacological treatment. Pulmonary rehabilitation can improve these symptoms. Unfortunately, not every patient with COPD is able to complete conventional training methods, due to exercise-induced dyspnoea. Resistance training and transcutaneous neuromuscular electrical stimulation are relative new training modalities in patient with COPD, which have shown to have positive effects on skeletal muscle function, exercise tolerance and health-related quality of life. To date, only high-frequency (> 50 Herz) is used. It is plausible to use low-frequency NMES (15 Herz) also, because of the decreased exercise tolerance.

Study objective

The purposes of this study are to study the effects of low-frequency NMES, high-frequency NMES and resistance training on health status, exercise tolerance and muscle strength in patients with COPD.

Study design

It concerns a prospective, single-blind randomized controlled trial.

Intervention

Resistance training of the lower-limb muscles.
Low-frequency (15 Herz) and high-frequency (75 Herz) transcutaneous electrical stimulation of the lower-limbs.

Study burden and risks

All interventions will be given at Ciro Horn as part of the regular clinical pulmonary rehabilitationprogramm.
The burden concerning the intervention is not more than in the regular pulmonary rehabilitationbecause of the shift towards interventions which cause less dyspnoea for the patients.

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

• Patients with a primary diagnosis of COPD according to the Global Initiative For Chronic Obstructive Pulmonary Lung Disease (GOLD) definition: Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible.The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases. COPD is diagnosed by a chest physician.
• Medical Research Council dyspnea scale (MRC) 4/5. COPD patients with grade 4 or 5 on the Medical Research Council (MRC) dyspnoea scale (*stops for breath after walking about 100 yards or after a few minutes on level ground* or *too breathless to leave the house, or too breathless when dressing or undressing*, respectively) have been shown to have a higher risk of having quadriceps weakness compared to COPD patients with lower MRC dyspnoea

grades, even after correction for the degree of airflow limitation. Almost 50% of the patients with MRC dyspnoea grade 4 or 5 has quadriceps weakness. Moreover, exercise intolerance and reduced health status have been related to higher MRC dyspnoea grades in patients with COPD.
• Muscle weakness of the lower limbs. Muscle strength and endurance will be measured with the Biodex.
• Informed consent for voluntary participation.
• To be able to communicate in the Dutch language.

Exclusion criteria

• Neuromuscular disorders. In neuromuscular disorders a (partial) paralysis will have consequences for the conductance speed of the nerves. The parameters of the treatment by NMES, which are mentioned in the research-protocol, can differ from the parameters which are necessary at neuromuscular disorders
• Joint disorders in hip, leg and/or knee. Probably these disorders need a different kind of therapy (for example water therapy). Thereby these disorders can ensure confounders in the measurements which to take place in the assessment.
• Metal implants in hip, leg and/or knee. Metal implants cause a disruption of the electric field. The field lines concentrate on metal. As a consequence overheating and damaging of the tissues around the metal can take place.
• Cardiac pacemaker or Internal Cardiac Defibrillator (ICD). Although the presence of safety studies patients with implantated pacemakers and ICDs will be excluded.
• Lack of motivation to participate voluntarily in this study.
• Patiënten with chronic oxygen suppletion will be xcluded for the measurements with the Oxycon Mobile.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2010
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	portable electrical stimulator and resistance training apparatus
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-03-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-11-2010
Application type:	Amendment
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: 23227
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL30153.068.09
OMON	NL-OMON23227