# 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.

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- 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...

**Ethische beoordeling** Positief advies

**Status** Werving nog niet gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

## **Samenvatting**

#### ID

NL-OMON23296

#### **Bron**

Nationaal Trial Register

#### **Aandoening**

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

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

#### **Ondersteuning**

Primaire sponsor: CIRO Horn

Overige ondersteuning: CIRO Horn

#### Onderzoeksproduct en/of interventie

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

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.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

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.

#### Doel van het onderzoek

- 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.

#### **Onderzoeksopzet**

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.

#### Onderzoeksproduct en/of interventie

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.

### Contactpersonen

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#### **Deelname** eisen

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

# Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

#### **Opzet**

Type: Interventie onderzoek

Onderzoeksmodel: Cross-over

Toewijzing: Gerandomiseerd

Blindering: Enkelblind

Controle: Actieve controle groep

#### **Deelname**

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 30-05-2018

Aantal proefpersonen: 15

Type: Verwachte startdatum

# **Ethische beoordeling**

Positief advies

Datum: 28-05-2018

Soort: Eerste indiening

## **Registraties**

#### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46386

Bron: ToetsingOnline

Titel:

#### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

#### In overige registers

Register ID

NTR-new NL7031

Register ID

NTR-old NTR7236

CCMO NL63531.100.17 OMON NL-OMON46386

# Resultaten

#### Samenvatting resultaten

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