Ventilation oxygen support for COPD

Gepubliceerd: 10-12-2015 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29565

Bron
NTR

Verkorte titel
VOS COPD

Aandoening

exertional hypoxemic COPD

Ondersteuning

Primaire sponsor: Philips Group Innovation - Research,
High Tech Campus 34
5656 AE Eindhoven, The Netherlands
Overige ondersteuning: Philips Group Innovation - Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the present study is to investigate whether or not patients with COPD with normal blood gases and static hyperinflation at rest, but hemoglobin oxygen

desaturation during exercise have beneficial effects of continuous or intermittent oxygen therapy combined with bilevel positive pressure non-invasive ventilation, in terms of time to recovery after exercise and duration of continuation of exercise after recovery.

Toelichting onderzoek

Doel van het onderzoek

Primary hypotheses

The primary hypothesis of the present study is that included patients who receive continuous or intermittent oxygen and bilevel positive pressure ventilation during fixed work rate treadmill exercise tests have shorter recovery time and/or longer duration of continuation of exercise after recovery compared to the sham setting. This hypothesis will be accepted based on the p values (accepted if p ¡Ü 0.05).

Secondary hypotheses

The first secondary hypothesis is that intermittent use of oxygen and bilevel positive pressure ventilation in included patients is non-inferior compared to continuous use of oxygen in terms of time to recovery after exercise.

Second, it is hypothesized that the use of continuous or intermittent oxygen and bilevel positive pressure ventilation in included patients is associated with significant positive effects on heart rate, heart rate recovery, exercise induced oxygen desaturation, exercise induced changes in transcutaneous measured pCO2, changes in breathing frequency, dynamic hyperinflation, dyspnea scores, leg discomfort. These hypotheses will be accepted based on the p values (accepted if ¡Ü 0.05).

Onderzoeksopzet

end of exercise on day 1 and day 2

Onderzoeksproduct en/of interventie

Ventilation and oxygen support during exercise.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects eligible for participation should meet the following criteria:

1. Patients with a diagnosis of COPD, which is spirometrically confirmed with FEV1/FVC ratio below 0.7 and staged as GOLD 2 or higher, which is FEV1 < 80% of predicted according to validated reference values.

2. Age between 40 and 80 years.

3. Normal blood gases at rest while breathing room air. Normal blood gases are defined as pO2 levels > 8.0 kPa and pCO2 levels below 6.5 kPa.

4. Pulseoxymetre measured hemoglobin oxygen desaturation during 6 minute walking distance below 88%.

5. Presence of static hyperinflation, measured as an increase in residual volume > 150% of predicte values according to validated reference values.

6. Stable state COPD, which is free from exacerbations or respiratory infections for at least two weeks.

7. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for subject selection

Subjects eligible for participation should not meet the following criteria:

1. Active malignancy

2. Previous pulmonary surgery

3. Unstable cardiovascular disease as unstable coronary artery disease, heartfailure or claudicatio intermittens as these might infere with the safety of the exercise.

4. Orthopedic problems that interfere with walking tests

5. Use of walking aids or wheel chair

6. Contraindications for use of non-invasive ventilation: acute sinusitis or otitis media, low blood pressure, inability to adequately clear secretions, etc..

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	Placebo

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	20-12-2015
Aantal proefpersonen:	13
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	10-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5251
NTR-old	NTR5508
Ander register	: 2014-0055 COPD Pilot

Resultaten