Ventilation oxygen support for COPD

No registrations found.

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

Summary

ID

NL-OMON29565

Source
NTR

Brief title
VOS COPD

Health condition

exertional hypoxemic COPD

Sponsors and support

Primary sponsor: Philips Group Innovation - Research,
High Tech Campus 34
5656 AE Eindhoven, The Netherlands
Source(s) of monetary or material Support: Philips Group Innovation - Research

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary objective of the study is to compare the intermittent use of oxygen and bilevel positive pressure non-invasive ventilation to continuous use, in terms of time to recovery after exercise and duration of continuation of exercise after recovery

Additional secondary objectives of the study are to investigate whether or not the interventions described in the primary objective have beneficial 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.

Study description

Study objective

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).

Study design

end of exercise on day 1 and day 2

Intervention

Ventilation and oxygen support during exercise.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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..

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	20-12-2015
Enrollment:	13
Type:	Unknown

Ethics review

Positive opinion

Date:	10-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results