A study to investigate intermittent and continuous oxygen and ventilation support during physical activity in exertional hypoxemic COPD patients

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To investigate whether or not COPD patients 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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43753

Source
ToetsingOnline

Brief title
Ventilation and oxygen support for COPD patients

Condition

- Other condition

Synonym
chronic obstructive pulmonary disease (COPD)

Health condition

chronic obstructive pulmonary disease (COPD)

Research involving

Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips Research;Eindhoven

Intervention

Keyword: Ambulatory and Intermittent, Exertional hypoxemic COPD, Hyperinflation, Positive pressure and Oxygen

Outcome measures

Primary outcome

To investigate whether or not COPD patients 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 transcutaneously measured pCO2, changes in breathing

frequency, dynamic hyperinflation, dyspnea scores, leg discomfort.

Study description

Background summary

The project is aimed to evaluate new opportunities for oxygen therapy/delivery for COPD management and the project is conducted with close consultation with Home respiratory care business. A detailed literature study is conducted for identifying the clinical needs of COPD patients and various Oxygen therapies [such as long term oxygen therapy, ambulatory oxygen therapy, short burst oxygen therapy] used in COPD management, which helps to relieve the symptoms such as breathlessness. And, the current study addresses one of the opportunity to move upstream from very severe to patients to less-severe/moderate patients and could be considered as a pilot study prior to a large clinical study.

Study objective

To investigate whether or not COPD patients 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.

Study design

A longitudinal, single blind, sham controlled, cross-over pilot study with 20 patients. This design was chosen to investigate the beneficial effects of the interventions compared to the sham situation in the individual patient..

Intervention

A commercially available CE certified Philips-Respironics V60 ventilator, connected to a wall supply of Oxygen will be used to provide the COPD patient with combined supplemental oxygen and ventilation support during six minute walk test.

Study burden and risks

There are no anticipated adverse device effects. Residual risks associated with investigational device are only minimal as we will only use CE marked devices

within their intended purpose, and make use of an application expert for set up and instruction. A combination of continuous positive air pressure during ventilation in combination with supplemental oxygen is expected to improve the exercise capacitance in these patients and probably also their recovery from exertion. These benefits outweigh the minimal risks associated with the treadmill walking tests.

Contacts

Public
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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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. No hypoxia requiring long term oxygen treatment and no hypercapnia. Normal blood gases are defined as pO2 levels * 7.3 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

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-02-2016
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	V60 ventilator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-06-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL54204.100.15