Pulmonary RehabIlitation with Nasal-high-flow-support in COPD and Effectiveness: The PRINCE study

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To determine the difference in increase in cycle endurance time after PR using NHF oxygen supplementation in patients during both exercise training and night time compared to patients using a conventional oxygen delivery systems.

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

Summary

ID

NL-OMON46686

Source
ToetsingOnline

Brief title
PR with NHF in COPD and Effectiveness

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: CIRO+ Horn
Source(s) of monetary or material Support: Ministerie van OC&W,Fisher & Paykel

Intervention

Keyword: COPD, Oxygen, rehabilitation

Outcome measures

Primary outcome

The main study parameter is the increase in cycle endurance time after completion of the PR program and 6 months after completion of the PR program.

Secondary outcome

Secondary study parameters are changes in 6-min walking distance (6MWD), increase in training intensity, oxygen saturation, heart rate, Borg scores for dyspnoea and fatigue, lung function, health status and the number of exacerbations and hospitalizations. Long term outcome measures for the follow-up period are lung function, cycle endurance time, daily symptoms and the number of exacerbations and hospitalizations.

Study description

Background summary

Exercise-based rehabilitation programs, which for an important part exist of endurance training, are able to partially improve quadriceps muscle strength and endurance, functional exercise performance and health status in patients with chronic obstructive pulmonary disease (COPD). Hypoxia or oxygen desaturation might be the limiting factor to exercise and increase in training intensity during pulmonary rehabilitation (PR). Newer devices that provide treatment with high flow, heated, humidified oxygen might help to prevent patients for from desaturation and increase the training intensity during PR. Indeed, Nasal High Flow (NHF) oxygen delivery systems have shown to improve endurance cycling time when applied in in laboratory settings. In addition, the night-time use of NHF oxygen delivery systems have been shown to improve symptoms and exacerbation frequency in patients with COPD. Continuous use during night and resting time of this device during and after PR at home could potentially help to maintain the beneficial effects of PR. However, the

effects of these devices have never been studied during and after PR in patients with COPD.

Study objective

To determine the difference in increase in cycle endurance time after PR using NHF oxygen supplementation in patients during both exercise training and night time compared to patients using a conventional oxygen delivery systems.

Study design

This is a prospective, single-blind, randomized controlled trial that will be conducted during a pulmonary rehabilitation program in CIRO+ Horn.

Intervention

Patients participating in a routine 40-session rehabilitation program at CIRO+ will be randomized to the use of nasal high flow (NHF) oxygen supplementation during both exercise training and night time or a conventional oxygen delivery system. Patients will continue to use NHF or the conventional system after PR at home and will be followed during 6 months.

Study burden and risks

The participants will be asked for one extra visit. The following outcomes will be measured after 6 months: lung function, cycle endurance time, daily symptoms, number of exacerbations and hospitalizations. Potential risks are environmental contamination and/or potential cross infection of pathogenic organisms, a dry or bloody nose, skin irritation from the nasal cannula and a fire risk.

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 COPD with hypoxia which at least demand 1 liter oxygen/min during baseline.
- Clinical stable on the basis of clinical picture by the chest physician.
- Documented desaturation during exercise, which demands at least 2 liters oxygen/min to correct.
- Permission for voluntary participation. Patient will be asked during the start of their rehabilitation program and have to sign an informed consent. Patients have the right to withdraw from the study without any negative consequences on their rehabilitation.
- Attending the regular rehabilitation program in CIRO+.

Exclusion criteria

- Lack of motivation for voluntary participation in the present study.
- Not capable to understand the instruction of the NHF oxygen delivery system
- Outpatient pulmonary rehabilitation program in a hospital which is part of the CIRO network.
- Not capable to perform cycle tests, walk tests and/or endurance training on a cycle ergometer and treadmill.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2019
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Airvo 2
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-11-2018
Application type:	First submission
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	NL64087.100.18