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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24905

Source
NTR

Brief title
PRINCE

Health condition

Chronic Obstructive Pulmonary Disease (COPD)

Sponsors and support

Primary sponsor: CIRO+ Horn
Source(s) of monetary or material Support: Fisher & Paykel

Intervention

Outcome measures

Primary outcome

The main study parameter is the increase in cycle endurance time after pulmonary

rehabilitation.

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

Rationale: 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 desaturation and increase the training intensity during PR. Continuous use of this device 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.

Objective: To determine the difference in increase in cycle endurance time after PR using NHF oxygen supplementation compared to conventional oxygen delivery systems.

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

Study population: Patients with COPD with hypoxia which requires at least 1 liter oxygen/minute in rest and 2 liters oxygen/minute during exercise, with documented desaturation during exercise. Patients will continue to use NHF or the conventional system after PR at home and will be followed during 6 months.

Intervention: Patients participating in a routine 40-session rehabilitation program at CIRO+ will be randomized to the use of nasal high flow (NHF) oxygen suppletion or a conventional oxygen delivery system.

Main study parameters/endpoints: The main study parameter is the increase in cycle endurance time after PR. 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

Increase in cycle endurance time after pulmonary rehabilitation using NHF oxygen supplementation will be larger compared to conventional oxygen delivery systems.

Study design

Baseline-8 weeks (after pulmonary rehabilitation)-6 months after pulmonary rehabilitation

Intervention

Patients participating in a routine 40-session rehabilitation program at CIRO+ will be randomized to the use of nasal high flow (NHF) oxygen suppletion or a conventional oxygen delivery system.

Contacts

Public
Centrum voor Integrale Revalidatie Orgaanfalen,
Postbus 4080
M. Sillen
Hornerheide 1
Horn 6080 AB
The Netherlands
+31 (0)475 587721
Scientific
Centrum voor Integrale Revalidatie Orgaanfalen,
Postbus 4080

M. Sillen
Hornerheide 1
Horn 6080 AB
The Netherlands
+31 (0)475 587721

Eligibility criteria

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.

- 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 because of severe hypoxia/hypercapnia, neuromuscular diseases, joint disorders in hip, leg and/or knee or severe breathlessness.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL7280
NTR-old	NTR7513
Other	: ABR nummer 64087

Study results