OPEP Therapy in COPD/chronic bronchitis patients with excess mucus

No registrations found.

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

Summary

ID

NL-OMON27221

Source
Nationaal Trial Register

Health condition

COPD
chronic bronchitis
sputum
airway clearance

COPD
chronische bronchitis
sputum
mucusklaring

Sponsors and support

Primary sponsor: Martini Hospital Groningen (department of Pulmonary Diseases)
Source(s) of monetary or material Support: Martini Hospital Groningen and an unrestricted grant from Trudell Medical International

Intervention

Outcome measures

Primary outcome

The primary endpoint is the mean CCQ Total score after 3 months.

Secondary outcome

The secondary endpoints at 3 months are:

- mean subdomain scores of the CCQ, respectively symptoms, mental and functional state.

- mean Leicester Cough Questionnaire (LCQ) total and domain scores.

- St. George’s Respiratory Questionnaire (SGRQ).

- A global rating of change in health status and in ability of coughing up sputum after 3 months will be used to evaluate self-perceived change.

- Lung function (spirometry, FEV1, FEV1%pred, FVC, FVC%pred).

- Exacerbation rate.

- Hospitalisation rate for COPD.

Study description

Background summary

Chronic mucus hypersecretion and impaired mucociliary clearance are hallmark features of the chronic bronchitis phenotype of Chronic Obstructive Pulmonary Disease (COPD). Chronic cough and excess mucus production have been found to be associated with patient-related outcomes such as exacerbations, hospitalisations, lung function decline and increased mortality. Therefore, airway clearance techniques like Oscillating Positive Expiratory Pressure (OPEP) therapy might play an important role in the management of patients with COPD or chronic bronchitis with chronic sputum production. However, evidence for the routine use of these devices in clinical practice is lacking.
Objective: To evaluate the effect of OPEP use on respiratory symptoms in patients with COPD or chronic bronchitis with excess mucus in daily clinical practice.

Study Design: A prospective randomised, double-blind, controlled trial.

Study Population: A total of 106 patients (of the department of pulmonary diseases of the Martini Hospital Groningen, the Netherlands) with COPD or chronic bronchitis (> 40 years of age) with excess mucus will be included.

Intervention: Patients will be allocated either to the intervention group (using a hand-held mechanical OPEP device) or the control group (using the sham version of the hand-held

device). Patients in both groups will be instructed to use the device 10 minutes twice daily for three months.

Outcomes: Data will be collected at baseline and after three months. The primary outcome is respiratory symptoms as measured by the Clinical COPD Questionnaire (CCQ). Secondary outcomes are cough symptoms (LCQ), health-related Quality of Life (SGRQ), global rating of change in health status and ability of coughing up sputum, lung function (FEV1 and FVC (L and % predicted)) and exacerbations. In addition data on adherence and patient satisfaction will be collected.

Relevance: This study might improve the management of patients with COPD or chronic bronchitis with excess mucus, since it will clarify the role of OPEP Therapy in this patient population in daily clinical practice.

Study objective

The objective of this prospective randomised, double-blind, controlled trial is to evaluate the effect of OPEP use on respiratory symptoms in patients with COPD or chronic bronchitis with excessive mucus in daily clinical practice.

Study design

The study will consist of two visits, a baseline visit and a follow up visit (3 months later).

At 6 weeks patients will fill out a short version of the questionnaire to be able to determine the timing of the effect of the OPEP device.

Intervention

Patients will be randomly allocated either to the intervention group (using a hand-held mechanical OPEP device, Aerobika) or the control group (using the sham version of the hand-held device).The sham version is an identically appearing device that has been adjusted (i.e. the system delivering the positive expiratory pressure is not working anymore but the system delivering the oscillation still works and therefore when using the device patients do hear a sound and feel vibrations comparable with the OPEP device used in the intervention group). At baseline, both groups will be provided with information on how to use and clean the OPEP system. During the study period (3 months) patients are instructed to use the OPEP system daily two times for ten minutes.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with COPD or bronchitis with excessive mucus will be included in this study.

Inclusion criteria

- Diagnosis: Patients with COPD or chronic bronchitis.

- Aged 40 years or older

- Excessive mucus

Exclusion criteria

Exclusion criteria

- Patiënts with CF

- Patients with bronchiectasis

- Patients who used OPEP in the past.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2015
Enrollment:	96
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-12-2015
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	NL5404
NTR-old	NTR5529
Other	: ABR 55392

Study results

Summary results
not yet