The effectiveness of an Oscillating Positive Expiratory Pressure (OPEP) Therapy on respiratory symptoms in patients with COPD/chronic bronchitis with excess mucus in daily clinical practice

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To evaluate the effect of OPEP use on respiratory symptoms in patients with COPD or chronic bronchitis with excess mucus in daily clinical practice.

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

Summary

ID

NL-OMON42501

Source
ToetsingOnline

Brief title
OPEP Therapy in COPD/chronische bronchitis patients with excess mucus

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, Chronic Obstructie Pulmonary Disease (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: het betreft een investigator-initiated onderzoek waarbij de personele kosten gemoeid met dit onderzoek door de afdeling Longziekten van het Martini Ziekenhuis worden gedragen. Om de extra kosten (van longfunctiemetingen;vragenlijsten;instructie van het OPEP systeem;onkosten van patiënten) te dekken is een unrestricted grant aangevraagd bij Trudell Medical International,Trudell Medical International (in de vorm van een unrestricted grant)

Intervention

Keyword: airway clearance, chronic bronchitis, COPD, sputum

Outcome measures

Primary outcome

Respiratory symptoms as measured by the Clinical COPD Questionnaire (CCQ).

Secondary outcome

Secondary outcomes are subdomainscores of the CCQ, health-related Quality of

Life (SGRQ), cough symptoms (LCQ), 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.

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.

Study 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.
The study will consist of two visits, a baseline visit and a follow up visit (3 months later).
At both visits lung function will be measured, and patients will be asked to fill out questionnaires with regard to symptoms (CCQ), cough symptoms (LCQ), health-related quality of life (SGRQ). At 6 weeks patients will fill out the CCQ questionnaire to be able to determine the timing of the effect of the OPEP device. In addition, at follow-up patients will be asked to rate their change in health and in ability to cough up sputum in the last 3 months (since the baseline visit) on a global rating of change questionnaire. Data on exacerbations, hospitalisation due to COPD, adherence with therapy and satisfaction with the device will be collected at the follow-up visit. Patients will be randomised at baseline to either the intervention group (using a hand-held mechanical OPEP device) or the control group (using the sham version of the hand-held device). Patients will be instructed to use the OPEP device for 3 months twice daily for 10 minutes.

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 (according to the standard guideline) to use the device twice daily for 10 minutes for three months.

Study burden and risks

Participating in this study does not involve any risk for patients. The OPEP device used in this study is registered and already being precribed in usual care and the measurements are not invasive (questionnaires) or routine measurements in these patients (spirometry). Patients will visit the hospital two times and fill out questionnaires. After 6 weeks patients will be send a short version of the questionnaire (symptoms and adherence) and after filling out these questionnaire patients may return the questionnaire in a prestamped envelope.
Patients are instructed to use the OPEP system for 3 months twice daily for 10 minutes. This is the standard use as prescribed in clinical practice. However,

patients in the control group will use an OPEP system without functional mechanisms. In our opinion the benefits of including a control group using a sham device (by preventing bias) outweights the disadvantages (asking patients twice daily for 10 minutes to use the device). Since we inform patients well and explain the reason for this, patients can consider this issue before they agree to participate. Although we realise that this might influence participation rate and adherence we emphasise the need for high quality studies in this area. This study might improve the management of patients with COPD or chronic bronchitis with excess mucus, since it will reveal the beneficial value of OPEP Therapy in this patient population in daily clinical practice.

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

clinical diagnosis of COPD or chronic bronchitis (aged 40 years or older)
patients with sputum production/excess mucus
informed consent

Exclusion criteria

diagnosis of CF or bronchiectasis
OPEP use in the past

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2016
Enrollment:	106
Type:	Actual

Medical products/devices used

Generic name:	Oscillatory Positive Expiratory Pressure device;Aerobika
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-12-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL55392.099.15
Other	studie zal worden geregistreerd in Nederlands Trial Register