OPEP Therapy in COPD/chronic bronchitis patients with excess mucus

Gepubliceerd: 13-12-2015 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27221

Bron
Nationaal Trial Register

Aandoening

COPD
chronic bronchitis
sputum
airway clearance

COPD
chronische bronchitis
sputum
mucusklaring

Ondersteuning

Primaire sponsor: Martini Hospital Groningen (department of Pulmonary Diseases)
Overige ondersteuning: Martini Hospital Groningen and an unrestricted grant from Trudell Medical International

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Longziekten - Martini Ziekenhuis

Siebrig Schokker
van Swietenplein 1

Groningen 9728 NT
The Netherlands

Wetenschappelijk

Longziekten - Martini Ziekenhuis

Siebrig Schokker
van Swietenplein 1

Groningen 9728 NT
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria

- Patiënts with CF

- Patients with bronchiectasis

- Patients who used OPEP in the past.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-12-2015
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-12-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5404
NTR-old	NTR5529
Ander register	: ABR 55392

Resultaten

Samenvatting resultaten
not yet