The influence of a Pulsating Electrostatic Field (PESF) on oxygen saturation, quality of life and exercise capacity of COPD patients, a single center, double blind, placebo controlled study.

Published: 30-08-2018
Last updated: 12-04-2024

Primary objectives:- improvement of oxygen saturation Secondary objectives:- improvement of quality of life- improvement of exercise capacity- improvement of muscle power- improvement of phase angle- registration of potential short term and long...

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

Summary

ID

NL-OMON46616

Source
ToetsingOnline

Brief title
Influence of PESF on oxygen saturation, QoL and exercise capacity in COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Heerenveen Ziekenhuis, De Tjongerschans
Source(s) of monetary or material Support: GLNP Medical Devices BV;levert het voor het onderzoek benodigde New Health 9000 apparaat zonder kosten en een 'unrestricted research grant'

Intervention

Keyword: Chronic bronchitis, Chronic Obstructive Pulmonary Disease, Pulsating Electrostatic Field

Outcome measures

Primary outcome

- oxygen saturation just before the first and immediately after the last

PESF/placebo treatment

- cap gas

- CCQ-score (quality of life)

- 6 minute walking test

- squeenze force

- phase angle (as a measurement for the muscle cell condition)

- lung function

Secondary outcome

- oxygen saturation during and up to 24 hours after the PESF/placebo treatments

Study description

Background summary

Treatment with PESF has been in use for many years for different clinical indications as well as by top athletes. It has been mainly used for quick recovery of the body, muscle damage or pain during and after strenuous exercise. In addition, positive influences of PESF treatments have been found

in diabetic patients, such as improvement of basal metabolic rate, improvement of wound repair of foot wounds, polyneuropathy and by promotion of microvascular blood flow. Also positive effects in COPD patients haven been found, such as stabilization or improvement of oxygen saturation, quality of life and exercise capacity. The mechanism of action is still unknown. The current hypothesis of the mechanism of action is the reduction of rouleaux formation of red blood cells by improvement of intracellular pH and improvement of the autonomous control of smooth muscle cells of the arterioles.

Study objective

Primary objectives:
- improvement of oxygen saturation

Secondary objectives:
- improvement of quality of life
- improvement of exercise capacity
- improvement of muscle power
- improvement of phase angle
- registration of potential short term and long term side effects

Study design

The study is designed as a single center, randomized, placebo-controlled, parallel study of 32 COPD GOLD class III and IV patients. 16 patients will undergo 3 PESF sessions of 30 minutes during 1 week and 16 patients will undergo 3 sham PESF sessions of 30 minutes. Before and after the PESF-treatments, lung function, squeeze force, phase angle, 6 minute walking test will be measured. The quality of life will be measured before, after and during the treatments. In addition, oxygen saturation will be measured continuously using a continuous oxygen saturation monitor.

Intervention

16 Patients will receive 3 PESF treatments in 1 week and 16 patients will receive 3 placebo treatments in 1 week.

Study burden and risks

Burden and risks of this research are negligible. Overall the patients will be done in 3 to 4 hours. The treatment itself lasts 30 minutes, most of the tests are non-invasive and most of them are already familiar to the patients. In addition, the treatment has no or hardly any side effects and the New Health 9000 (Akern) has a CE quality mark. The patient will be asked to use the continuous oxygen saturation monitor at home, which may be considered

unpleasant.

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

- 40-85 years old
- Male and female
- COPD patients, post-bronchodilator FEV1/FVC <70%, and FEV1 < 50%predicted oxygen saturation without suppletion * 90% (home use of oxygen suppletion is allowed, but will be stopped during PESF-treatment)
- Stable medication (no foreseeable need to change therapy)
- Able to understand the purpose and method of research after adequate information and to ability to decide on participation

- Signed form of consent

Exclusion criteria

- Known malignant condition with limited life expactancy
- Carrier of electrical equipment (pacemaker, ICD etc.)
- COPD exacerbation in the last 3 weeks
- Participation in other research
- Woman who are pregnant, breastfeeding or of childbearing age without effective contraception unless they meet the postmenopausal definition: 12 months of natural omenorrhea or 6 months of spontaneous ammenorrhea with serum FSH>40 mIU/mL or the use of one or more of the following acceptable methods of birth control: a) surgical sterilication, b) hormonal contraception, c) barrier methods: condom or occlusion cap with spermicide, d) constant abstention.
- Manifest acute inflammation
- Patients with manifest decompensatio cordis
- Rehabilitation/reactivation programs within 2 months before or during the study

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2019
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	New Health 9000 for the application of a negatively charged;pulsating electrostatic field (PESF)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL64047.042.17