

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

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Primary objective:- Improvement of walking distance in 6MWT immediately after the first treatment and cumulatively after 3 consecutive treatments with PESF
Secondary objectives:- improvement of oxygen saturation - improvement of quality of life...

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

Summary

ID

NL-OMON54846

Source

ToetsingOnline

Brief title

COPD and PESF

Condition

- Bronchial disorders (excl neoplasms)

Synonym

chronic obstructive lungdisease, COPD

Research involving

Human

Sponsors and support

Primary sponsor: OLVG

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 Obstructive Pulmonary Disease, Exercise capacity, Pulsating Electrostatic Field

Outcome measures

Primary outcome

Primary study parameter is distance measured in 6MWT immediately after the first treatment and cumulatively after 3 consecutive treatments with PESF.

Secondary outcome

- Quality of life (CCQ) and BORG score as measured in 6MWT
- Oxygen saturation during and up to 24hours after the PESF/ Sham treatment
- spirometry and diffusion
- phase angle

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.

A pilot study showed an improvement of exercise capacity, (temporary improvement of) oxygen saturation, and quality of life, seen in a small group of the same research population. Whether this temporary effect of 6 hours on oxygen saturation has an effect on the distance to walk with the 6MWT is insufficiently clear. It is speculative to assume that the walking distance and oxygen saturation are independent parameters.

The question of whether the effect of PESF on the 6MWT is temporary (6 hours) or longer, is now unknown and has not been included in the analysis.

Study objective

Primary objective:

- Improvement of walking distance in 6MWT immediately after the first treatment and cumulatively after 3 consecutive treatments with PESF

Secondary objectives:

- improvement of oxygen saturation
- 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

Single center, randomized, sham controlled, crossover study in 34 patients with COPD GOLD III / IV, with a walking distance in the 6MWT <500m. These patients will initially be randomized into 2 groups. Group 1 will be treated with PESF for 30 minutes in 3 consecutive sessions, in a working week. Group 2 will undergo 3 sham sessions of 30 minutes in the same way. After a "wash-out" period of 30 days, group 1 will be treated with sham sessions and group 2 with PESF. Ultimately, therefore, each participant will be exposed to both PESF and a sham procedure. The study will be conducted at the OLVG hospital, location Oost in Amsterdam.

Intervention

Group 1 will be treated with PESF for 30 minutes in 3 consecutive sessions, in a working week. Group 2 will undergo 3 sham sessions of 30 minutes in the same way. After a "wash-out" period of 30 days, group 1 will be treated with sham

sessions and group 2 with PESF.

Study burden and risks

Burden and risks of this research are negligible. The PESF treatment takes 30 minutes; the outcome tests are non-invasive. In addition, the PESF treatment has no relevant side effects. The PESF machine (New Health 9000, Akern) is CE qualified.

After treatment, the patient will use the continuous oxygen saturation monitor at home for 24 hours, which may be considered unpleasant.

Contacts

Public

OLVG

Oosterpark 9
Amsterdam 1091 AC
NL

Scientific

OLVG

Oosterpark 9
Amsterdam 1091 AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- 40-85 years old
- Male and female
- COPD patients, postbronchodilator FEV1/FVC <70%, and FEV1 < 50%predicted.
- 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 expectancy
- 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 amenorrhea or 6 months of spontaneous amenorrhea with serum FSH>40 mIU/mL or the use of one or more of the following acceptable methods of birth control:
 - a) surgical sterilization,
 - b) hormonal contraception
 - c) barrier methods: condom or occlusion cap with spermicide
 - d) constant abstinence.
- 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:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-04-2022
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	New Health 9000 for the application of a negatively
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	12-12-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	16-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

CCMO

ID

NL70664.100.19

Study results

Date completed:

07-05-2024

Summary results

Trial ended prematurely