Evaluation of the effect of the AlphaCoreTM on breathlessness and time to discharge in hospitalised subjects with COPD.

No registrations found.

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

Summary

ID

NL-OMON26499

Source
NTR

Brief title
AlphaCore study

Health condition

COPD patient that are hospitalised with an exacerbation

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: ElectroCore LLC

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the time to discharge. This will be measured in days from

the day of admission. If a patient is admitted between 2400 h and 1200 h, the day of admission is counted as 1 day; if the patient is admitted after 1200 h, the day of admission is counted as 0.5 days.

Secondary outcome

1. Breathlessness, measured through the BORG scale from 0 (no breathlessness) until 10 (extreme breathlessness), before and after (sham)stimulation;

2. Change in breathlessness (Borg score), measured in hours;

3. Airway resistance, measured with Forced Oscillation Technique (FOT);

4. Description of position of the vagal nerve, on the left and right side of the neck, through a one-time ultrasound examination;

5. Adverse Events.

Study description

Background summary

Evaluation of the effect of the AlphaCoreTM on breathlessness and time to discharge in hospitalised subjects with COPD".

Rationale:

The main reason for subjects with COPD to be hospitalised is a COPD exacerbation, which is accompanied by increased breathlessness. Standard treatment options include oral prednisolon, antibiotics (oral or intravenously), and bronchodilation. Discharge from the hospital is mainly determined by the recovery from breathlessness. On average subjects remain admitted for 8-9 days. When use of the AlphaCoreTM reduces breathlessness, it is assumed that time to discharge is shortened.

Objective:

To assess the effect of using the AlphaCoreTM devices, as adjunctive treatment to regular care, on time to discharge in hospitalised subjects with COPD.

Study design:

This study will be designed as a prospective balanced controlled trial. In the intervention group the AlphaCoreTM will be used, as adjunctive treatment to regular care. Subjects in the control group will receive regular care and sham stimulation. Balancing (mininisation) is a form of randomisation, and will be used to distribute the subjects on both groups. With the help of the a minisation program the potential confounders (e.g. GOLD classification, age) will be balanced over both groups.

Study population:

52 subjects for the study will be recruited from the department of pulmonary medicine at Medisch Spectrum Twente in Enschede, the Netherlands. Subjects will be subjects with a diagnosis of COPD, who are admitted to wards A4 or C4.

Intervention:

Intervention subjects will receive vagus nerve stimulation three times a day, according to the device instructions of the AlphaCoreTM, starting on the first day following admission, until the day of discharge. The control subjects will receive identical care, but with sham stimulation three times a day.

Main study endpoints:

The primary outcome measure is the time to medical discharge. This will be measured in days from the day of admission.

Study objective

N/A

Study design

Only during hospitalisation.

Intervention

Intervention subjects will receive non-invasive vagal nerve stimulation three times a day, according to the device instructions, starting on the first day following admission, until the day of discharge.

The control subjects will receive identical care, but with sham stimulation, three times a day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 40 years, male or female;

2. Ability to understand and read Dutch;

3. Diagnosis of COPD stage II, III or IV according to GOLD;

4. Hospitalised at ward A4 or C4;

5. Is able to give written informed consent;

6. Borg score <3 at the first day of hospitalization.

Exclusion criteria

1. Has an abscess or other infection or lesion (including lymphadenopathy) at the AlphaCore™ treatment site;

2. Is currently implanted with an electrical and/or neurostimulator device, such as cardiac pacemaker, defibrillator, vagus neurostimulator, deep brain stimulator, spinal stimulator, bone growth stimulator, or cochlear implant;

3. Subjects with metal implants including but not limited to stents, bone plates and bone screws, at or near the treatment area;

4. Has a history of carotid endarterectomy or vascular neck surgery on the right side;

5. A history of syncope or seizures during last year.
Use of beta blockers;

6. Known carotid artery stenosis.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2012
Enrollment:	52
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-06-2012
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	NL3354
NTR-old	NTR3486
Other	METC Medisch Spectrum Twente : P12-015
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A