Treatment of Central Sleep Apnea Syndrome with low-pressure nasal continuous positive airway pressure and rebreathing.

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Primary objective:To show that addition of dead space to low-pressure nCPAP (which is usually not effective but can be relatively well tolerated) makes the therapy effective and diminishes the apnea hypopnea index with >10/hour in patients with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Sleep disturbances (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON39400

Source
ToetsingOnline

Brief title
CSAS treated with rebreathing and nCPAP.

Condition

- Sleep disturbances (incl subtypes)

Synonym
sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: stichting pulmo science

Intervention

Keyword: central sleep apnea, CO2, dead space, rebreathing

Outcome measures

Primary outcome

Primary study parameters/endpoints

Apnea Hypopnea Index with low-pressure nCPAP and added dead space versus

low-pressure nCPAP only

Secondary outcome

Secondary study parameters/endpoints

* Blood pressure measured during low-pressure nCPAP with added dead space and

low-pressure nCPAP only.

* Sleep structure during low-pressure nCPAP with added dead space and

low-pressure nCPAP only.

* Subjective quality of sleep during low-pressure nCPAP with added dead space

and low-pressure nCPAP only.

* Heartrate variability during low-pressure nCPAP with added dead space and

low-pressure nCPAP only.

Study description

Background summary

Central sleep apnea syndrome (CSAS) is characterized by recurrent central apneas during sleep. A central apnea is a cessation of airflow for at least ten seconds without respiratory efforts. The syndrome is often accompanied by a disturbed sleeping pattern and excessive daytime sleepiness. Treatment of CSAS

is difficult. Continuous positive airway pressure (CPAP), bi-level positive airway pressure (BIPAP), oxygen and several drugs have been applied with variable success. Additional CO2 can prevent apneas since the arterial CO2 pressure (PaCO2) is continually held above the apnea- threshold. This is the PaCO2 below which breathing is no longer stimulated by CO2. When during sleep PaCO2 drops below the apnea-threshold because of deep breathing, a central apnea occurs. This can be prevented by adding CO2. With a rebreathing/dead space mask, the patient breathes CO2 he has produced himself, and doesn*t need a CO2 gas cylinder. Preliminary studies show that a rebreathing/dead space mask may be effective in both CSAS and in Cheyne-Stokes breathing in heart failure.

Study objective

Primary objective:
To show that addition of dead space to low-pressure nCPAP (which is usually not effective but can be relatively well tolerated) makes the therapy effective and diminishes the apnea hypopnea index with >10/hour in patients with CSAS.

Secondary Objective:
To show that addition of dead space to low-pressure nCPAP in patients with CSAS improves sleep structure.

To show that addition of dead space to low-pressure nCPAP in patients with CSAS improves blood pressure.

To show that addition of dead space to low-pressure nCPAP in patient with CSAS improves the quality of sleep(Groningen Sleep Quality Scale)

To show that addition of dead space to low-pressure nCPAP in patients with CSAS improves the heartrate variability.

Study design

Series of n of 1 studies.
Each patient acts as his or her own control and receives 5 pairs of treatments. Each pair consists of a one night period of treatment with dead space and low-pressure nCPAP and one night of treatment with low-pressure nCPAP only. The latter is considered a placebo therapy since the pressure of 4 cm H2O is considered ineffective. For each pair of treatments the order of low-pressure nCPAP and low-pressure nCPAP with added dead space will be randomized. The random sequence will be prepared in advance by a pulmonary function technician for each patient separately. The patient and the investigator are unaware of the sequence of treatment.

Intervention

Each patient acts as his or her own control and receives 5 Pairs of treatments. Each pair consist of one night treatment with low pressure CPAP with added dead space(rebreathing) and a one night treatment with low pressure CPAP only. For each pair of treatments the order of dead space with low pressure CPAP or low pressure CPAP only was randomized.

Study burden and risks

Benefit is adequate treatment for CSAS in the future. The advantage of the n of 1 study is that we can investigate if this treatment is beneficial in this specific person. The risk of participating in this study is low. Patients could have a raise in their PaCO2 that is more than expected. This is prevented by adjusting the dead space volume in such a way that the end-tidal CO2 does not raise more than 5mmHg. The first time of sleeping with added dead space(rebreathing) to low-pressure nCPAP will be monitored in hospital for safety reasons. Furthermore It can be expected that patients with adequately functioning chemoreflexes (normocapnic during daytime) increase their tidal volumes during sleep to such an extent that severe hypercapnia will not occur. Every day polygraphy and capnography will be performed at the patients home. When a patient feels short of breath, this can be solved by breathing through the mouth instead of the nose. Patients have to sleep in hospital 2 times and visit the out-patient clinic 2 times. A researcher will visit the patients home every day for 10 days. In a recent study 204 patients were treated with added dead space to cpap and no patient experienced headache because of hypercapnia.

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

outpatients diagnosed with central sleep apnea syndrome by polysomnography with sleep apnea index *15 and at least 50% of all apneas is central in origin without obstructieve components.
Age 18-80 years
Patients are using or have been using CPAP.
Informed Consent

Exclusion criteria

History of heart failure, cardiac arrhythmia or cardiac ischemia,
History of stroke
Cheyne Stokes breathing during daytime,
Sedatives or hypnotic agents, opioids.,
Respiratory failure(hypoxia, hypercapnia or respiratory acidosis during daytime)
Pulmonary diseases
Body mass index * 30
Untreated thyroid disease
pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	nasal mask with tube;whisper valve and CPAP(4cmH2O)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-10-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	02-09-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	NL32398.094.10