

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

Published: 23-10-2012

Last updated: 01-05-2024

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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Sleep disturbances (incl subtypes)
<b>Study type</b>	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, CO<sub>2</sub>, 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 CO<sub>2</sub> can prevent apneas since the arterial CO<sub>2</sub> pressure (PaCO<sub>2</sub>) is continually held above the apnea- threshold. This is the PaCO<sub>2</sub> below which breathing is no longer stimulated by CO<sub>2</sub>. When during sleep PaCO<sub>2</sub> drops below the apnea-threshold because of deep breathing, a central apnea occurs. This can be prevented by adding CO<sub>2</sub>. With a rebreathing/dead space mask, the patient breathes CO<sub>2</sub> he has produced himself, and doesn't need a CO<sub>2</sub> 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 H<sub>2</sub>O 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 PaCO<sub>2</sub> that is more than expected. This is prevented by adjusting the dead space volume in such a way that the end-tidal CO<sub>2</sub> 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  $\geq 15$  and at least 50% of all apneas is central in origin without obstructive 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  $\geq 30$

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

CCMO

### ID

NL32398.094.10