The regulation of end-tidal carbon dioxide by dynamic rebreathing for patients with central sleep apnea.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON48946

Source
ToetsingOnline

Brief title
Dynamic rebreathing for CSAS

Condition

- Sleep disorders and disturbances

Synonym
Central sleep apnea - sleep disorder

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Geld van Universiteit Twente aan ziekenhuis vanwege afstudeerstage Technische Geneeskunde student (A.C. Zekveld)

Intervention

Keyword: central sleep apnea, dynamic rebreathing, PETCO2, regulation

Outcome measures

Primary outcome

The main study parameters are the ability to regulate PETCO2, quantified by the percentage of time spent in predetermined patient specific PETCO2 range, and the user experiences, quantified by a numeric rating scale based questionnaire.

Secondary outcome

Secondary study parameters are the differences between the control night and intervention night of the following parameters:

Apnea/hypopnea index (AHI)

Central apnea/hypopnea index (CAHI)

Central apnea index (CAI)

Central hypopnea index (CHI)

Arousal index (AroI)

Mean ventilation (L/min)

Percentage of total sleep time (TST) with oxygen desaturation (SpO2<90%)

Total duration of CSR divided by TST

Percentages of TST spent in each sleep stage (N1, N2, N3 and REM)

Loop gain, defined as the hyperpnea length/cycle length of CSR

Study description

Background summary

Central sleep apnea syndrome (CSAS) is a sleep related breathing disorder based on a disturbed respiratory regulation. This regulation is predominantly based on the partial pressure of carbon dioxide of the arterial blood (PaCO2). A disturbance in PaCO2 can result in Cheyne Stokes respiration (CSR); the alternation of hyperventilation and apneas. Symptoms include sleep disruption, excessive daytime sleepiness and insomnia. Current treatment is continuous positive airway pressure (CPAP) therapy, although for many patients it seems not effective enough. Several studies are performed to investigate an alternative method to treat CSAS. Supplementary carbon dioxide (CO2) seems effective. Dynamic setups have benefit over static ones, since the CO2 can be closely controlled. In addition, the use of dead space or rebreathing is preferred over gas mixers, because gas mixers are expensive and inhalation of excessive CO2 is imminent. A new setup is developed to regulate the pressure of end tidal CO2 (PETCO2) by means of dynamic rebreathing, without the use of gas mixers.

Study objective

The feasibility of the new device is investigated. The primary objective includes the ability to regulate nocturnal PETCO2 in patients with CSAS and the user experiences. Secondary objectives concern the differences in CSAS parameters, e.g. apnea/hypopnea index (AHI), CSR, arousal index (AroI) and loop gain.

Study design

This is a feasibility study with a novel intervention.

Intervention

The intervention is the regulation of nocturnal PETCO2 during one night by means of a new setup based on literature. The dynamic rebreathing setup consists of a sealed CPAP masker, capnograph, tubes and a valve system to be able to regulate the partition of room air and rebreathed air. The regulation is based on real time measurement of PETCO2. A reference PSG (usual care) is used to measure PETCO2 during the night while only room air is inhaled, to determine the target PETCO2 and associate range. Dynamic rebreathing with the new setup takes place to regulate PETCO2 during the second PSG.

Study burden and risks

With elevation of PaCO2 sympathetic nerve activity can occur. It is however intended to regulate and stabilize PaCO2. With malfunctioning of the new device inhalation of excessive CO2 is imminent, this risk is minimalised to closely

monitor the patient and parameter values during the night. On top of that, the patient is always able to breathe in room air through the mouth when necessary. Whenever the PETCO2 increases over 7.5 kPa or SpO2 < 80% for longer than 30 minutes or an event (e.g. severe arrythmias) requiring immediate intervention.

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

*18 years of age
Hypocapnic central sleep apnea syndrome (CSAS) (i.e. AHI* 15, *50% central events, central apnea index *5, presence of > 15% Cheyne Stokes respiration(CSR))
Written informed consent from the subject prior to participation
CPAP nasal mask use * 4 hours/night for * 5 days a week.

Exclusion criteria

Unable to understand and read the Dutch language
Hypercapnia during daytime (PaCO2 * 6 kPa) and/or metabolic compensation (bicarbonate > 27 mmol/l)
Hypercapnia during the reference PSG (mean PETCO2 * 6.3 kPa during N2 sleep excluded from CSR and apnea)
History of neuro(muscular) disease and/or kyphoscoliosis
NYHA Functional Classification class IV
Chronic obstructive pulmonary disease stage 3 / 4 (GOLD-criteria)
Drug abuse
Use of drug with known influence on respiratory drive that cannot be stopped one week prior to the PSGs (e.g. analeptics and opioids)
Patients breathing through the mouth during sleep (according to CPAP read-out or their own / partner*s experience)
Pregnant women

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2019
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Dynamic rebreathing setup
Registration:	No

Ethics review

Approved WMO Date:	23-05-2019
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27892
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65541.044.18
Other	NL7633
OMON	NL-OMON27892