Dynamische regulatie van koolstofdioxide bij patiënten met centraal slaapapneu.

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The new device is able to regulate the PETCO2 and to keep the PETCO2 in the predetermined range.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27892

Bron
NTR

Verkorte titel
Dynamic rebreathing by CSAS

Aandoening

Central sleep apnea - sleep disorder

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: initiator sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.
In this study 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.

Doel van het onderzoek

The new device is able to regulate the PETCO2 and to keep the PETCO2 in the predetermined range.

Onderzoeksopzet

T0 = First appointment, study is explained, informed consent is signed, baseline characteristics and arterial and capillary blood gas analysis are performed.
T1 = Control night. A week after T0 the control PSG night takes place.
T2 = Intervention night. Within a week after T1 the intervention PSG night takes place.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥ 18 years of age
- Hypocapnic CSAS (i.e. AHI ≥15, ≥ 50% central events, CAI ≥ 5, presence of >15% Cheyne Stokes Respiration)
- Written informed consent (IC) from the subject prior to participation
- CPAP nasal mask use ≥ 4 hours/night for ≥ 5 days a week.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 night (based on own experience or partner's experience)
- Patients breathing through the mouth during sleep (according to CPAP read-out or their own / partner's experience)
- Pregnant women

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2019
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
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Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48946
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7633
CCMO	NL65541.044.18
OMON	NL-OMON48946

Resultaten

Samenvatting resultaten
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