# Dynamische regulatie van koolstofdioxide bij patiënten met centraal slaapapneu.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27892

**Source**
NTR

**Brief title**
Dynamic rebreathing by CSAS

**Health condition**

Central sleep apnea - sleep disorder

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente
**Source(s) of monetary or material Support:** initiator sponsor

### Intervention

### 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.
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.

### Study objective

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

### Study design

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.

### 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.

## Contacts

**Public**
Medische Spectrum Twente
Gerike Buitenhuis

053 487 2000
**Scientific**
Medische Spectrum Twente
Gerike Buitenhuis

053 487 2000

## Eligibility criteria

### Inclusion criteria

- ≥ 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.

### 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 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

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2019 |
| Enrollment: | 5 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**

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# Ethics review

Not applicable

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|---|---|
| Application type: | Not applicable |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 48946
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results

**Summary results**
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