Sleep Position Device Versus Continuous Positive Airway Pressure in Mild to Moderate Central Sleep Apnea
A Randomized Trial

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sleep position device is an effective treatment alternative in central positional sleep apnea syndrome

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

Samenvatting

ID

NL-OMON20065

Bron
Nationaal Trial Register

Verkorte titel
central positional apnea trial

Aandoening

central positional sleep apnea syndrome

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: NONE

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

AHI (apnea-hypopneas/hour) at 3 months and at 12 months will be compared to baseline. Succesfull treatment is defined as a reduction in AHI to < 5 events per hour at 3 months. Or either a 50% reduction in baseline AHI or a ≥ 10 decrease in AHI combined with improvement in ESS (≥ 2 points). The proportion of patients reaching succesfull treatment in both treatment arms will be compared using Fisher's exact test. Relative risk of succesfull treatment between both treatment arms will be calculated and 95% Confidence interval of the risk difference.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: To perform a randomized prospective trial comparing long-term outcomes in CPAP versus SPD (night balance) in central positional apnea patients.

Study design: A single-centre randomised prospective trial between CPAP and sleep position device treatment. Randomisation was stratified according to BMI and smoking. Physician and patients are not blinded to the treatment arms. Written patient informed consent is obtained. Diagnosis at baseline is by polysomnography. Eligible patients are randomized to either standard CPAP therapy or SPD treatment.

Epworth Sleepiness Scale (ESS) is measured at baseline and subsequently under treatment at 3 and 12 months. Polysomnography for AHI measurement is repeated under treatment at 3 and 12 months.

Study population: All patients with central positional sleep apnoea, with an AHI ≥ 5 and ≤ 30, are included in the study. Central sleep apnoea is defined as: AHI ≥ 5 with 50% or more of events occurring without any respiratory effort. And associated with symptoms of either excessive sleepiness or disrupted sleep. Positional sleep apnoea is defined as having a supine AHI≥2x AHI non-supine with ≥10% and ≤ 90% supine sleep.

Intervention (if applicable): Patient informed consent is obtained. Participants are assigned to either sleep position device (Night-Balance, Night Balance b.v., The Hague, The Netherlands) or CPAP (standard of care arm).

Doel van het onderzoek

sleep position device is an effective treatment alternative in central positional sleep apnea syndrome

Onderzoeksopzet

MEC approval expected within 3 months. First patient randomized expected within 6 months. Study completion expected within 3 years. no interim analysis planned.

Onderzoeksproduct en/of interventie

Participants are assigned to either sleep position device (Night-Balance, Philips, The Netherlands) or CPAP (standard of care arm).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Patients with central positional sleep apnoea are included in the study.
2. Apnoehypopneuindex ≥ 5 AND ≤ 30.
3. Patient age ≥ 18.

Central sleep apnoea is defined as: AHI ≥ 5 with 50% or more of events occurring without any respiratory effort. And associated with symptoms of either excessive sleepiness or disrupted sleep.

Positional sleep apnoea is defined as having a supine AHI≥2x AHI non-supine with ≥10% and ≤ 90% supine sleep

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. chronic respiratory insufficiency (paCO2 > 6kPA)
2. BMI ≥ 30
3. Left sided valvular heart disease > mild
4. Patients with symptomatic heartfailure (AHA stadium C)
5. Night or rotating shift work
6. Active psychiatric disease
7. Seizure disorder
8. Medication use for sleeping disorders
9. Previous treatment with CPAP or sleep position device
10. Simultaneous other OSAS treatments
11. Pregnancy
12. Coexistent non-respiratory sleep disorders (e.g. insomnia, periodic limb movement disorder, narcolepsy) that would influence functional sleep assessment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	27-02-2020
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49557
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8397
CCMO	NL70711.099.19
OMON	NL-OMON49557

Resultaten

Samenvatting resultaten
Final results will be published in peer reviewed medical journal