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 can be used to treat positional obstructive mild to moderate central sleep apnea syndrome.1-5 Efficacy in positional central sleep apnea syndrome is unkown. Apnea is positional in 56% of the cases, meaning the events do not…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49557

Source
ToetsingOnline

Brief title
CSAS

Condition

- Other condition

Synonym
central sleep apnea

Health condition

centraal slaap apneu

Research involving

Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: geen subsidie

Intervention

Keyword: mild to moderate central sleep apnea, sleep position device

Outcome measures

Primary outcome

Primary study parameters

AHI at 3 months and at 12 months will be compared to baseline using students t-test. 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) .20,21 The proportion of patients reaching succesfull treatment in both treatment arms will be compared using Chi square test.

Secondary outcome

Secondary study parameter(s)

total central AI, total central AHI, AHI supine , AHI non supine, supine central AHI, non-supine central AHI, ESS, total sleep time supine, total sleep time non-supine will respectively be compared to baseline at resepectively 3 months and 12 months using student t-test.

Other study parameters

General baseline measurements: age, sex, weight, height, BMI, active

smoking yes/no will be compared between treatment arms using student t-test

for continuous parameters and Fisher's Exact test for categorical variables.

Study description

Background summary

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

A sleep positional device can be used to treat positionally obstructive mild to moderate central sleep apnea syndrome.1-5 Efficacy in positional central sleep apnea syndrome is unknown. Apnea is positional in 56% of the cases, which means that the events do not occur when you sleep on the side. NightBalance developed a sleeping place device for these patients. The small lightweight device is worn in a belt around the chest, reminding the patient with gentle vibrations not to sleep on their backs. These soft vibrations do not disturb the sleep quality. It is a small device and is worn at the front of the body in a comfortable, adjustable chest strap. It has smart algorithms that automatically adjust the vibration strength to each individual, and intelligent patterns that avoid habituation and result in long-term compliance.

CPAP is standard treatment in the central sleep apnea syndrome.6-11 The CPAP is a small box with a motorized fan in it. This fan draws in air from the chamber, pressurizes it gently and then delivers it to a pressure setting specifically tailored to the needs of the patient. The air inlet segment of a CPAP machine has a filter to eliminate the absorption of dust, smoke or other impurities in the air. The CPAP machine has a humidification chamber built into the box. Water is heated here to moisten the compressed air before it is delivered. A hose is attached to the CPAP machine that connects the box to a CPAP mask. The CPAP mask and CPAP machine settings are made on the patient during a clinical CPAP start night at the hospital sleep center.

Study objective

sleep position device can be used to treat positional obstructive mild to moderate central sleep apnea syndrome.1-5 Efficacy in positional central sleep apnea syndrome is unkown. Apnea is positional in 56% of the cases, meaning the events do not occur when sleeping on the side. For these patients NightBalance developed a sleep position device. The small lightweight device is worn in a

belt around the chest, reminding the patient with gentle vibrations to not sleep on their back. These gentle vibrations do not disrupt sleep quality. It is a small device, and is worn on the front side of the body in a comfortable, adjustable, chest band. It has smart algorithms that automatically adjust the vibration strength to each individual, and intelligent patterns that avoid habituation and result in long term compliance.

CPAP is standard of care treatment in central sleep apnea syndrome.6-11 The CPAP is a small box which has a motorized fan inside. This fan draws air from the room, gently pressurizes it, then delivers it at a pressure setting specific to the needs of the patient. The air intake section of a CPAP machine has a filter on it to eliminate the intake of dust, smoke, or other impurities in the air. The CPAP machine has a humidification chamber built into the box. This is where water is warmed to humidify the pressurized air before it is delivered. Attached to the CPAP machine is a hose which connects the box to a CPAP mask. The CPAP mask and CPAP machine settings are fitted to the patient during a clinical CPAP start night at the sleep centre in our hospital.

Study design

Epworth Sleepiness Scale (ESS) wordt gemeten bij aanvang en vervolgens onder behandeling op 3 en 12 maanden. Polysomnografie voor AHI-meting wordt herhaald onder behandeling na 3 en 12 maanden.
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 burden and risks

no risk, low burden, at the follow-u[after 3 and 12 months an extra polysomnography is performed.

Contacts

Public
Martini Ziekenhuis

Van Swietenlaan 1
Groningen 9728 NT
NL
Scientific
Martini Ziekenhuis

Van Swietenlaan 1
Groningen 9728 NT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients with central positional sleep apnoea are included in the study.
2. Apnoehypopneuindex >= 5 AND <= 30.
3. Patient age >= 18.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2020
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Generic name:	Sleep position device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-02-2020
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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: 20065
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70711.099.19
Other	volgt
OMON	NL-OMON20065