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Sleep position device versus continuous positive airway pressure in central sleep apnea

Submission date
06/11/2023

Recruitment status
Recruiting

Registration date
11/12/2023

Overall study status
Ongoing

Last Edited
05/12/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnea syndrome is caused by upper airway obstruction during sleep due to muscle relaxation. Central sleep apnea syndrome is caused by a lack of respiratory effort during sleep. In positional sleep apnea syndrome, apneas are relieved by sleeping in a non-supine position. A sleep position trainer is an effective treatment for positional obstructive sleep apnea syndrome. However, it has not been tested in positional central sleep apnea syndrome. This study aims to test the efficacy of a sleep positional trainer in positional central sleep apnea syndrome.

Who can participate?
Adult patients with mild to moderate positional central sleep apnea syndrome

What does the study involve?
Participants will be allocated to treatment with either a sleep position device (Nightbalance, Philips, The Netherlands) or continuous positive airway pressure (CPAP).

A sleep position device can be used to treat patients with mild to moderate obstructive sleep apnea syndrome. Sleep apnea is often not present in such patients in the side position and the device trains patients to sleep more in the side position. The effect of a sleep position device has been well-studied in obstructive sleep apnea syndrome. The effect on central sleep apnea syndrome is not known.

A sleeping position device is a small, flat, lightweight device. This is worn at the front in a soft band around the chest. Through light vibrations, the device reminds the patient not to sleep on their back but on their side. These light vibrations do not disturb sleep quality. The strength of the vibrations is adjusted to the individual patient by smart algorithms. The result is that this treatment is usually well tolerated in the long term.

CPAP is currently the standard treatment for central sleep apnea patients. CPAP is a small box with a motorized fan inside. This fan draws air from the room. The air pressure is then slowly increased by the device. The air is then delivered at an air pressure adjusted specifically to the patient's needs. There is a filter on the device that filters out dust, smoke and other impurities in

the air. Built into the CPAP machine is a humidifier. The CPAP device has an air hose that connects the device to the CPAP mask. The CPAP device and mask are adjusted to the patient's needs during a CPAP adjustment period through the Martini Hospital Sleep Center.

What are the possible benefits and risks of participating?
It is important that participants carefully weigh the possible pros and cons before deciding to take part. A possible advantage of participating in this study is that treatment with a sleep position trainer is better tolerated than standard treatment with CPAP.

A risk may be that treatment with a sleep position trainer will prove less effective than treatment with a CPAP. In that case, participants will be treated suboptimally for a period during the research period and complaints of sleep apnea syndrome may persist for longer. Another disadvantage of participating in the study is that they will have polysomnography done twice where this is otherwise not always necessary.

The sleep position trainer or CPAP device can cause side effects.

These adverse effects are common (affecting 1 in 10 people or more) with a sleep position trainer:
1. The sleep apnea syndrome may not be sufficiently corrected and fatigue may then remain present to some extent
2. Only 71% of patients manage to use the sleep position trainer regularly

These adverse effects are common (affecting 1 in 10 people or more) with CPAP:
1. Stuffy nose
2. Running nose
3. Dry mouth
4. CPAP mask pressure on the face
5. CPAP mask leakage
6. Bothered by noise from the CPAP box

These adverse effects occur with CPAP, but not as often:
1. Irritated eyes
2. Suffer from cold air
3. Difficulty breathing out
4. Bronchitis complaints
5. Anxiety complaints

The sleeping position trainer may also have adverse effects that are still unknown. The effects of the sleep position trainer have not yet been sufficiently investigated in position-dependent central sleep apnea syndrome. The efficacy may be less than the efficacy of CPAP in this condition.

Where is the study run from?
This study is performed by the pulmonologists and ENT doctors of the Sleep Center of the Martini Hospital, Groningen, The Netherlands.

When is the study starting and how long is it expected to run for?
June 2019 to January 2027

Who is funding the study?
This study is funded by the Research Department of the Department of Pulmonary Medicine, Martini Hospital Groningen, The Netherlands

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Sleep position device versus continuous positive airway pressure in mild to moderate central sleep apnea: a randomized trial

Acronym
SPCSA

Study objectives
A sleep position trainer is an effective treatment for positional central sleep apnea syndrome equivalent to continuous positive airway pressure (CPAP)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/02/2020, Regionale Toetsingscommissie Patientgebonden Onderzoek (RTPO MCL. 3 e etage Dunantflat, Postbus 888, Leeuwarden, 8901 BR, Netherlands; +31 058 2861151; RTPO@zbn.nl), ref: NL70711.099.19

Study design
Single-centre randomized prospective trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Positional central sleep apnea syndrome

Interventions
This is a single-centre randomised prospective trial between CPAP and sleep position device treatment.

Written patient informed consent will be obtained. Diagnosis at baseline is by polysomnography. Randomisation will be stratified according to BMI and smoking. Physicians and patients are not blinded to the treatment arms. 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.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase III

Drug/device/biological/vaccine name(s)
Sleep Position Trainer (NightBalance, Philips, Netehrlands)

Primary outcome measure
The total apnea-hypopnea index (AHI) measured using polysomnography at baseline, 3 months and 12 months

Secondary outcome measures
1. Total central AI, total central AHI, AHI supine, AHI non-supine, supine central AHI, non-supine central AHI, total sleep time supine, total sleep time non-supine measured using polysomnography outcome parameters which are scored manually by scorers blinded to the treatment arm
2. Sleepiness measured using the Epworth Sleepiness Scale (ESS) at baseline and 3 and 12 months
3. Compliance measured using digital use readings from the Night-Balance sleep position device and CPAP machine at 3 and 12 months follow-up
4. Other study parameters: General baseline measurements: age, sex, weight, height, BMI, active smoking yes/no

Overall study start date
10/06/2019

Completion date
01/01/2027

Eligibility

Key inclusion criteria
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

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
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 heart failure (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

Date of first enrolment
01/03/2020

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
Martini Hospital
Wetenschapsbureau Martini Ziekenhuis
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Sponsor information

Organisation
Martini Ziekenhuis

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Sponsor type
Hospital/treatment centre

Website
https://www.martiniziekenhuis.nl/onderzoek

ROR
https://ror.org/017b69w10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Martini Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
01/07/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication