Analysis of the clinical effects of head positional therapy with the Sleep Position Trainer Wave in the treatment of Positional Obstructive Sleep Apnea

Published: 03-02-2014
Last updated: 22-04-2024

Evaluation of the effect of positional therapy with the SPT Wave on sleep apnea severity, i.e. re-duction of the apnea-hypopnea index (AHI).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40474

Source
ToetsingOnline

Brief title
Sleep Position Trainer Wave for POSA patients

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)

Synonym
POSA (positional obstructive sleep apnea)

Health condition

Obstructief Slaap Apneu Syndroom

Research involving

Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: Nightbalance,NightBalance B.V.

Intervention

Keyword: Positional Obstructive Sleep Apnea (POSA), positional therapy, SPT Wave

Outcome measures

Primary outcome

Primary endpoints; reduction of PSG parameters, in particular AHI, AI, HI, DI,

reduction of % of sleeping supine sleep position of the head, without

disturbance of the sleep quality.

Secondary outcome

Secondary endpoints: Outcome of Quality of Life questionnaires; Epworth

Sleepiness Scale (ESS), Functional Outcomes of Sleep Questionnaire (FOSQ),

Subjective Treatment Satisfaction Questionnaire (STSQ) . Compliance and

learning effect will also be evaluated after 50 days usage.

Demographic parameters: Sex, age, length, weight, BMI, alcohol intake,

medication will also be noted.

Study description

Background summary

Fifty-six percent of patients with Obstructive Sleep Apnea (OSA) are position dependent,
defined as having an Apnea hypopnea index (AHI), which is at least twice as high in supine sleeping position compared to the AHI during sleep in other positions. Standard therapy for patients with mild or moderate positional OSA

(POSA) is treatment with an Oral Appliance Trainer (OAT) or surgery. Recently the Sleep Position Trainer (SPT) has been studied for patients with POSA. In this research a new device that uses auditory stimulation, the SPT Wave, will be introduced for patients with POSA.

Study objective

Evaluation of the effect of positional therapy with the SPT Wave on sleep apnea severity, i.e. re-duction of the apnea-hypopnea index (AHI).

Study design

Multicentre clinical trial

Intervention

A new product for head positional therapy, the SPT Wave, has been developed based on the same working principle of the Sleep Position Trainer but now focusing specifically on head positional therapy. The SPT Wave is placed on the temporal bone, lateral from the eyes. It measures the head sleeping position and gives the patient auditory stimulation feedback when the patient*s head is in the supine position. The patient is then able to react to the auditory signal and turn the head or head and trunk into a non-supine position. The PSG with the SPT Wave will be repeated after 50 days of usage and the results will be compared with the baseline PSG.

Study burden and risks

The risks for patients participating in this study are negligible. Inconveniences of the SPT Wave can be discomfort caused by irritation of the band, difficulties with an increased sleeping period with the head in non-supine sleeping position or difficulties sleeping with the SPT Wave, as well as possible irritation in the ear canal or from the sound. This can be compensated by the expected improvement of sleep quality caused by the therapy.

Contacts

Public
Sint Lucas Andreas Ziekenhuis

Molengraaffsingel 12-14
Delft 2629 JD
NL
Scientific

Sint Lucas Andreas Ziekenhuis

Molengraaffsingel 12-14
Delft 2629 JD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

+ 18 years and older.
+ Ability to speak, read and write the local country*s language (Dutch, French or Spanish depending on the country).
+ Ability to follow up.
+ Diagnosis with symptomatic mild or moderate OSA (5 < AHI < 30).
+ Diagnosis of 10 to 90% head supine position during the night.
+ AHI head supine is 2 > as high as AHI non-supine.
+ AHI head and trunk supine is 2 > as high as AHI non-supine.
+ Own a Windows PC and ability to install SPT connection software and upload research data.
+ Expected motivation to wear the SPT Wave for 50 days.
+ Expected to maintain current lifestyle (sports, medicine, diet etc.).
+ Normal audiogram for both ears

Exclusion criteria

- Central Sleep Apnea Syndrome.
- Night or shifting work.
- Medical history of known causes of tiredness by day or severe sleep disruption (insomnia, PLMS, Narcolepsy).
- Seizure disorder.
- Known medical history of mental retardation, memory disorders or psychiatric disorders.

- Inability to provide informed consent.
- Simultaneous use of other treatment modalities to treat OSA.
- Hearing loss, wearing other ear devices.
- Anatomic ear abnormalities which influences correct attachment of the SPT Wave to the head and ear
- BMI above 35
- Extreme Migraine

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	SPT Wave
Registration:	No

Ethics review

Approved WMO

Date:	03-02-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL44820.029.13