Study with the SleepAssist in patients with Positional Obstructive Sleep Apnea.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21528

Source
NTR

Brief title
TSC-CL-001

Health condition

Positional Obstructive Sleep Apnea (POSA)

Sponsors and support

Primary sponsor: The Sleep Company B.V.
Source(s) of monetary or material Support: The Sponosr: The Sleep Company

Intervention

Outcome measures

Primary outcome

To demonstrate the primary objective of this investigation, the following primary endpoint will be evaluated:
A reduction in number of AHI events/hr greater than 10, or the percentage of reduction in AHI events/hr greater or equal than 50% in comparison to baseline.

Baseline data for the primary endpoint will come from the Baseline PSG, that is recorded before the SleepAssist device is activated (Day 1). Results will be measured at the end of the study, the Final PSG (day 25/26 +/- 7days):
The primary endpoint is defined the proportion of participants responders to the SleepAssist device. Responders will be defined as follow:
- Reduction in number of Apnea-Hypopnea index (AHI) events/hour greater than 10
- Or a reduction in AHI events/hour greater or equal than 50% in comparison to baseline
The AHI is the number of apneas or hypopneas recorded during the study per hour of sleep. It is expressed as the number of events per hour.
The main analysis of the primary endpoint will be conducted on the FAS population with the strategy missing=failure.
The proportion of responder and non-responder participants will be described (n and %) with its associated 95% Confidence Interval.
Number of AHI will also be described as a quantitative variable at baseline and at day 24. Comparison between values at Day 24 and baseline will be done using a paired Student test (parametric test) or Wilcoxon test (nonparametric test) depending on the distribution of the variable.
Based on the AHI, the severity of obstructive sleep apnea is classified as follows (29):
- None/Minimal: AHI < 5 per hour
- Mild: AHI ≥ 5, but < 15 per hour
- Moderate: AHI ≥ 15, but < 30 per hour
- Severe: AHI ≥ 30 per hour
The severity of obstructive sleep apnea will be described as a qualitative variable.

Secondary outcome

Secondary endpoints
Efficacy
Secondary endpoints that will be assessed related to secondary efficacy objectives are:
o ≥ 50% reduction in TST in supine position compared to baseline, based on PSG results
o % of compliant subjects (compliance defined as ≥ 4 hrs of sleep on SleepAssist for 7 nights/week), based on SleepAssist data
Safety
Related to safety the following secondary endpoints will be evaluated:
o Assess (serious) adverse events (AE), (serious) adverse device effects (ADE) and device deficiencies (DD)
o Assess presence of pressure points using the decubitus Pressure Ulcer Grading Chart or EPUAP (28)

Results from the first secondary endpoint will come from the same PSG results as described for the primary endpoint, with the same timelines.
Compliance will be checked at the end of the study. As the device is designed to register sleep data, compliance will be collected by registering the date and time that subjects are lying on the SleepAssist. (reaad out after day 25/26).
AEs will be checked during the entiire period the SleepAssist device is used. (from day 1 up to day 25/26).
To assess pressure points on subject’s skin, an examination of the skin at the level of the

subject’s back and shoulders will be performed at baseline (enrolment visit) and during the final visit (day 25/26)to evaluate the presence of decubitus. The European Pressure Ulcer Advisory Panel (EPUAP) classification considers 4 categories (I – IV) of decubitus starting with the lowest category of decubitus (class I), being the least severe form of decubitus.

Study description

Background summary

A single-arm, single-center, intra-patient, controlled investigation to show the efficacy of the SleepAssist device in reducing AHI events in patients suffering from POSA through polysomnography (PSG) analysis.
The primary objective of this investigation is to demonstrate that the SleepAssist device is effective in reducing events as measured by the apnea-hypopnea index (AHI) during sleep in POSA patients.
Main secondary objectives of this investigation are to confirm the device is safe and well tolerated by patients, and to evaluate two additional important factors for the efficacy of positional therapy, namely:
– To show that patients move from supine position to a different sleeping position
– To evaluate compliance
Approximately 67 subjects will be enrolled to be able to have 50 evaluable subjects. The subjects will go through a screening period where POSA will be diagnosed with PSG. After this, the subject will start sleeping on the SleepAssist device. First, while sleeping on an inactive device, a home PSG will be done as baseline. Then there is a 1 week training period, followed by a 15 day therapeutic period. After this, a final PSG will be performed.

Study objective

The SleepAssist device is effective in reducing events as measured by the apnea-hypopnea index (AHI) during sleep in POSA patients.

Study design

See the primary and secundary endpoints.

Intervention

Sleeping on the SleepAssist device

Contacts

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Eligibility criteria

Inclusion criteria

Main inclusion criteria • Subject is ≥18 years of age.
• Treatment naïve, i.e. no prior or current (P)OSA treatment
• a BMI (Body Mass Index) < 35
• Diagnosis of POSA through PSG analysis that was carried out within 8 weeks of enrolment, meeting all the following criteria:
o AHI (supine position) > 2 times higher than AHI (non-supine position)
o AHI (lateral) ≤10 per hr
o AHI ≥5 per hr and <30 per hr (mild to moderate severity)
o % Supine sleeping time between 10 and 90% of the Total Sleeping Time (TST)
• Understands the study protocol and is willing and able to comply with study requirements and sign informed consent.

Exclusion criteria

Main exclusion criteria • A female of child-bearing potential that is pregnant, as confirmed by urine pregnancy test, or intends to become pregnant, or is breast-feeding
• Chronic Obstructive Pulmonary Disease, COPD Gold Class > 2
• Cardiac failure, NYHA class > II
• Chronic Renal Failure, G2 class > 2
• Uncontrolled Diabetes Mellitus type I or II
• Joint, muscle or bone abnormalities due to orthopaedic conditions or rheumatic diseases that impair the sleeping position of the patient
• Hemoglobinopathies (e.g. sickle cell disease)
• Anaemia
• Active oncological disease or active/ongoing treatment for oncological disease
• Use of prescription opioids
• Oxygen use

• The presence of any other sleep disorder (central sleep apnoea, periodic limb movement disorder, clinical diagnosis of insomnia or narcolepsy)
• Any other major congenital or chronic disease which is not well controlled on the day of enrolment
• Major surgical procedures, which might affect sleeping or sleeping position, within 4 weeks of enrolment, or planned within the study period
• Excessive alcohol consumption (>4 drinks/day and/or >21 drinks/week)
• The use of any illegal drug(s), per subject report
• Night or rotating shift work at screening or planned during the study period
• Subject requires use of more than 2 pillows under the head while sleeping or sleeps in a bed/chair with raised upper body position
• Subject sleeps on a waterbed

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):	01-09-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-12-2020

Application type: First submission

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
NTR-new	NL9171
Other	MEC-United : TSC-SL-001

Study results