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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21528

Bron
NTR

Verkorte titel
TSC-CL-001

Aandoening

Positional Obstructive Sleep Apnea (POSA)

Ondersteuning

Primaire sponsor: The Sleep Company B.V.
Overige ondersteuning: The Sponosr: The Sleep Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

See the primary and secundary endpoints.

Onderzoeksproduct en/of interventie

Sleeping on the SleepAssist device

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9171
Ander register	MEC-United : TSC-SL-001

Resultaten