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Comparison of the NightBalance Lunoa to Positive Airway Pressure (PAP) for the Treatment of Positional Obstructive Sleep Apnea (POSA)

Submission date	Recruitment status	[X] Prospectively registered
18/04/2018	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
27/04/2018	Stopped	[_] Results
Last Edited	Condition category	[_] Individual participant data
10/05/2024	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive sleep apnea (OSA) occurs in up to 10% of the general population and is characterised by repetitive pauses of breathing during sleep due to obstruction of the upper airway. Approximately 35% of patients with OSA have the majority of their events when sleeping on their back, called Positional OSA or POSA. The best available treatment for OSA is Continuous Positive Airway Pressure (CPAP) which is a pump that provides a positive flow of air to keep the airway open. Oral appliances and surgery are also options, but are not as commonly used.
In the case of POSA, therapies that discourage patients sleeping on their back, such as tennis balls and positional belts that place an obstruction to supine sleeping on the patients back, have shown promise. However, patients often struggle to use these devices due to discomfort when they attempt to change position during the night. The device in this study, called SPT avoids this problem by discouraging POSA patients from sleeping on their back by delivering a vibrational stimulus, via a small device which is worn in a chest strap during sleep, each time the patient rolls to their back. This prompts the patient to roll over onto their side. Although several positive studies on the safety and efficacy of the SPT exist, these only focus on patients with mild and moderate disease.
This study aims to assess the effectiveness and adherence of the Lunoa SPT over 3 months of use compared to PAP for the treatment of POSA.

Who can participate?
Adults that suffer from Positional Obstructive Sleep Apnea

What does the study involve?
Participants are randomly allocated to receive one of two treatments, either Automatic Positive Airway Pressure (APAP) or Lunoa Sleep Position Therapy for a three month period.
Participants are sent home with instructions to use that device nightly at home for three months. After three months of using the first device, they return to the doctor for assessment of

the efficacy of the device using a sleep test and the compliance read from the device.
Upon conclusion of the first three month treatment period, patients receive the alternative treatment for a further three months.
At the end of the second three month period, participants return to their doctor again to assess the efficacy of the last device and read the compliance.
Before any treatment and after each treatment, patients undergo a sleep test and complete some questionnaires. During each treatment period, patients complete a healthcare utilization diary and report any problems.

What are the possible benefits and risks of participating?
Previous research has suggested that the SPT may provide as good a treatment as CPAP for Obstructive Sleep Apnea but, because the device is more comfortable participants might be able to use it for longer each night. However, this cannot be guaranteed.
Participants may be at risk of unwanted side-effects to the treatments administered in the study. These may include:
1. During the sleep test, skin irritation may occur at the site(s) where the electrodes and sensors are placed. If irritation occurs, it's usually minor and only lasts for a short time. Additional risks from a sleep study are minimal.
2. During the sleep test, they may experience difficulty falling asleep or sleeping with the study device(s) in place.
3. With the SPT device participants may experience:
o Irritation at the area where the device is worn
o Possible shoulder or hip discomfort from sleeping on their side more than normal
4. With the APAP device participants may experience
o Irritation at the area where the mask or nasal pillows are worn
o Irritation or discomfort from the air pressure of the device
There may be side effects that are not known at this time.

Where is the study run from?
The study is run from centers in France, the UK and Germany.

When is the study starting and how long is it expected to run for?
April 2018 to January 2021 (updated 24/06/2019, previously: January 2020)

Who is funding the study?
Philips (updated 24/06/2019, previously: NightBalance)

Who is the main contact?
Ellen Dutman
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(updated 24/06/2019, previously:
K. van der Geest
research@nightbalance.com)

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04211350

Secondary identifying numbers
EU-2018-001

Study information

Scientific Title
A Multi-center, Prospective, Randomized Crossover Study with the NightBalance Lunoa SPT Compared to Positive Airway Pressure (PAP) for the Treatment of Positional Obstructive Sleep Apnea (POSA)

Acronym
SLEEP ON your SIDE (SOS)

Study objectives
The primary objective of the study is to assess the efficacy and adherence of the Lunoa SPT over 3 months of use compared to PAP for the treatment of POSA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/08/2018, Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; 0207 1048056; NRESCommittee.EastofEngland-CambridgeEast@nhs.net), ref: 18/EE/0201

Study design
Multi-center interventional prospective randomised 3-month crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Sleep apnea

Interventions
Participants are randomised to receive either Automatic Positive Airway Pressure (APAP), the gold standard treatment for Obstructive Sleep Apnea (OSA), or Lunoa Sleep Position Therapy for a three month period, stratified by site and treatment group with 50% of the patients in each arm.
Participants are sent home with instructions to use that device nightly at home for three months. After three months of using the first device, they return to the doctor for assessment of the efficacy of the device using a sleep test and the compliance read from the device.
Upon conclusion of the first three month treatment period, patients receive the alternative treatment for a further three months.
At the end of the second three month period, participants return to their doctor again to assess the efficacy of the last device and read the compliance.

At baseline and after each treatment, patients undergo a polysomnography test and complete a battery of questionnaires. During each treatment period, patients complete a healthcare utilization diary and report any adverse events. Upon conclusion of each treatment period, patients have the data downloaded from their treatment device.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
1. Severity of sleep apnea is measured using apnea-hypopnea index (AHI) measured with polysomnography at baseline and at the end of each 3-month treatment arm
2. Adherence is measured by downloading the data from the devices at the end of each 3-month treatment period

Secondary outcome measures

1. Daytime sleepiness is measured using ESS at baseline and at the end of each 3 month treatment arm.
2. Impact of sleepiness on activities of daily living is measured using FOSQ at baseline and at the end of each 3 month treatment arm.
3. Health related quality of life is measured using EQ-5D at baseline and at the end of each 3 month treatment arm.
4. Fatigue is measured using Pichot Fatigue Scale at baseline and at the end of each 3 month treatment arm.
5. Quality of life is measured using SF-36 at baseline and at the end of each 3 month treatment arm.
6. Patient Comfort and Satisfaction is measured using Likert scales at baseline and at the end of each 3 month treatment arm.
7. Mean Disease Alleviation is calculated using the AHI and adherence data at the end of each 3-month treatment arm
8. Adverse events are recorded at the end of each 3-month treatment arm
9. Health Economics and Resource Utilization are assessed using healthcare utilization diary which is completed by patients during each 3-month treatment arm

Overall study start date
01/04/2018

Completion date
31/01/2021

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Subject is adult
2. Either:
2.1. Treatment naïve, or
2.2. PAP non-complier (defined as current AAP user with <3 hours per night in the last 3 months per compliance download), and willing to use the APAP device per protocol
3. Diagnosis of POSA meeting all the following criteria per control PSG within 6 months of screening:
3.1. AHI of >15 during PSG with symptoms of sleepiness per Investigator discretion, or AHI of >15 during respiratory polygraphy with comorbidities (e.g. atrial fibrillation, resistant hypertension, etc.)
3.2. Supine AHI at least twice the lateral AHI
3.3. Lateral AHI <10
3.4. Supine time >30% and <70%
4. Understands the study protocol and is willing and able to comply with study requirements and sign informed consent. APAP non-compliant subjects must be willing to use their APAP device per protocol.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 (95 treatment naive & 55 PAP non-complier patients)

Key exclusion criteria
1. Prior or current therapy or treatment for OSA (for Treatment naïve group); Greater than an average of 3 hours per night of APAP use (in the APAP non-complier group)
2. A female of child-bearing potential that is pregnant or intends to become pregnant
3. Any unstable or severe medical condition of any organ system that at the discretion of the site Principal Investigator (PI) might affect the patient's participation in the study or generalization of treatment results
4. Taking medication that at the discretion of the site Principal Investigator (PI) might affect the patient's participation in the study or generalization of treatment results
5. Oxygen use
6. The presence of any other sleep disorder (central sleep apnea (CSA >5), periodic limb movement disorder (PLMAI >15), clinical diagnosis of insomnia or narcolepsy)
7. Excessive alcohol consumption (>21 drinks/week)
8. The use of any illegal drug(s), per subject report
9. Night or rotating shift work
10. Severe claustrophobia
11. Shoulder, neck, or back complaints that restrict sleeping position
12. Subject requires use of more than 2 pillows under the head while sleeping or sleeps in a bed /chair with raised upper body position

Date of first enrolment
01/08/2018

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
England

France

Germany

Scotland

United Kingdom

Wales

Study participating centre
Centre Hospitalier Universitaire Grenoble Alpes
Grenoble
France
38700

Study participating centre
Royal Papworth Hospital
Cambridge
United Kingdom
CB23 3RE

Study participating centre
Guy's and St. Thomas
London
United Kingdom
SE1 7EH

Study participating centre
Angers Centre Hospitalier Universitaire
Angers
France
49100

Study participating centre
Hôpitaux de Marseille Centre Hospitalier Universitaire
Marseille
France
13005

Study participating centre
Hopital Foch, Suresnes
Suresnes
France
92150

Study participating centre

Hôpital Bichat – Claude-Bernard
Paris
France
75877

Study participating centre
Universitätsmedizin Mannheim
Mannheim
Germany
68167

Study participating centre
Schlafmedizinisches Zentrum Regensburg
Regensburg
Germany
93053

Study participating centre
Hospital Bethanien Solingen
Solingen
Germany
42699

Study participating centre
Royal infirmary of Edinburgh
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Prince Philip Hospital
Llanelli
United Kingdom
SA14 8QF

Study participating centre

Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
North Tyneside General Hospital
Tyneside
United Kingdom
NE29 8NH

Study participating centre
Hôpitaux de Bordeaux Centre Hospitalier Universitaire
Bordeaux
France
33000

Study participating centre
Hôpital Universitaire Pitié - Salpêtrière (UPMC)
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Sponsor information

Organisation
Philips

Sponsor details
Philips Innovation Site Eindhoven
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Sponsor type
Industry

ROR

https://ror.org/02p2bgp27

Funder(s)

Funder type
Industry

Funder Name
Philips

Alternative Name(s)
Koninklijke Philips N.V., Royal Philips, Royal Philips N.V., Philips & Co

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 10/05/2024:

As the study was terminated and there was a limited number of participants enrolled, we do not plan to publish the results.

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Previous publication and dissemination plan:

Planned publication in a peer-reviewed journal.

Intention to publish date
31/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Jean Louis Pepin, jpepin@chu-grenoble.fr.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Plain English results			10/05/2024	No	Yes