ISRCTN56755910 https://doi.org/10.1186/ISRCTN56755910

Long-term safety and efficacy of positional therapy

Submission date	Recruitment status	[X] Prospectively registered
09/05/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/05/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/07/2020	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 long-term safety and effectiveness of the Lunoa SPT for the treatment of POSA.

Who can participate?
Adults with obstructive sleep apnea

What does the study involve?
Participants receive the Lunoa Sleep Position Therapy device for a minimum of two years. They are instructed to use the device nightly. Participants have a follow up appointment once every 12 months, where they undergo a sleep test, complete questionnaires and have the data downloaded from the device to check usage.

What are the possible benefits and risks of participating?
Participants may benefit if the SPT provides effective treatment of their POSA and they are able to use it for longer each night as compared to CPAP. Subjects may also benefit from the

increased medical contact during the study period.
There are no additional risks to participating in the study beyond those that would occur if the patient was being treated with the investigational device in routine clinical practice. The SPT is a low risk device.
There is an increased time and cost burden to the patient due to additional visits to the hospital, although the protocol has been designed to include the minimum number of hospital visits within which the research question can be reasonably be answered. Reasonable patients out of pocket expenses are reimbursed by the funder. Sites are required to provide this reimbursement initially and then invoice the funder monthly.
Patients may wish to continue using the SPT following the completion of the study. The funder will sign over the SPT devices of patients who wish to continue and are using this device within its current intended use, to their treating hospital. Patients who wish to continue using the SPT device who are not using it within its current intended will need to wait until the CE mark has been updated after which, the funder will sign over their SPT device to their treating hospital, and the device will be returned to them. The decision as to whether the patient continues with the SPT will be at the discretion of the physician and patient.

Where is the study run from?
1. Antwerp University Hospital (Belgium)
2. OLVG West (Netherlands)
3. Royal Papworth Hospital (UK)
4. Guy's and St. Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
February 2018 to September 2023

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

Who is the main contact?
Prof Olivier Vanderveken (Scientific)
olivier.vanderveken@uza.be

Contact information

Type(s)
Scientific

Contact name
Prof Olivier Vanderveken

Contact details
Faculty of Medicine and Health Sciences
University of Antwerp
Department of ENT, Head and Neck Surgery
Antwerp University Hospital UZA
Wilrijkstraat 10
Antwerp
Belgium

B-2650 Edegem
+ 32 3 821 33 84
olivier.vanderveken@uza.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EU-2018-002

Study information

Scientific Title
Observational study investigating the long term safety and efficacy of the sleep position trainer in patients with positional obstructive sleep apnea

Acronym
ORACLE

Study objectives
The primary objective of the study is to assess the long-term safety and efficacy of the Lunoa SPT for the treatment of POSA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2018, Ethics committee UZA/UA (Antwerp University Hospital, Ethics committee, Wilrijkstraat 10, 2650, Edegem, Belgium; +32 3 821 3897; EthischComite@uza.be), ref: B300201838420 (= Belgian registration number) and 18/39/421 (internal reference number)

Study design
Long-term multi-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

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
Positional Sleep Apnea

Interventions
All participants receive the Lunoa Sleep Position Therapy for a minimum two-year period. Participants are sent home with instructions to use their device nightly. At baseline and each 12-month interval, participants undergo a polysomnography test, complete a battery of questionnaires, are questioned about the occurrence of adverse events and have their compliance data downloaded from the device.

Intervention Type
Device

Primary outcome measure
1. Apnea–Hypopnea (AHI) obtained from a polysomnography (PSG) sleep study at baseline and each 12 month interval.

Secondary outcome measures
1. Efficacy of the device is measured using Epworth Sleepiness Scale (ESS), Pichot Fatigue Scale, Health and Anxiety Scale (HAD) at baseline and each 12 month interval
2. Quality of Life is measured using Functional Outcomes of Sleep Questionnaire (FOSQ) and Short-Form 36 questionnaires (SF-36) at baseline and each 12 month interval
3. Compliance is measured from the device download at each 12 month interval
4. Safety is assessed by recording adverse events (AE) at each 12 month interval
5. Comfort and satisfaction of participant is measured using the Visual Analogue Scale (VAS) at each 12 month interval

Overall study start date
01/02/2018

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Adult patients with a diagnosis of supine-dependent OSA defined as;
1.1. an AHI supine ≥ 2x AHI non supine, or,
1.2. AHI non-supine < 10/h and an AHI supine ≥ 10/h,
1.3. and 10 – 90 % supine sleep during PSG.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. A female of child-bearing potential that is pregnant or intends to become pregnant.
2. 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.
3. 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.
4. Oxygen use
5. The presence of any other sleep disorder (central sleep apnea (CSA >5), periodic limb movement disorder (PLMAI >15), clinical diagnosis of insomnia or narcolepsy)
6. Excessive alcohol consumption (>21 drinks/week)
7. The use of any illegal drug(s), per subject report.
8. Night or rotating shift work.
9. Severe claustrophobia.
10. Shoulder, neck, or back complaints that restrict sleeping position.
11. Subject requires use of more than 2 pillows under the head while sleeping or sleeps in a bed /chair with raised upper body position.
12. Driving risk: any car accident or near miss accident caused by sleepiness in the last 12 months and upon PI discretion

Date of first enrolment
01/09/2018

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Belgium

England

Netherlands

United Kingdom

Study participating centre

Antwerp University Hospital UZA (PI)
Belgium
B-2650 Edegem

Study participating centre
OLVG West
Netherlands
1061 AE Amsterdam

Study participating centre
Royal Papworth Hospital
United Kingdom
CB23 3RE

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

Sponsor information

Organisation
Philips

Sponsor details
Philips Innovation Site Eindhoven
High Tech Campus 37
Eindhoven
Netherlands
5656 AE

Sponsor type
University/education

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

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 Olivier Vanderveken, ENT Head and Neck Surgeon (olivier.vanderveken@antwerp.be)
Antwerp University Hospital UZA
Faculty of Medicine and Health Sciences
University of Antwerp
Wilrijkstraat 10
B-2650 Edegem

IPD sharing plan summary
Available on request