ReVENT Sleep Apnea System, a Minimally Invasive Approach to treat Obstructive Sleep Apnea: a Prospective Multicenter Post-Marketing Observational Study

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To assess the effectiveness and patient perception of benefit of the ReVENT Sleep Apnea System in patients diagnosed with Obstructive Sleep Apnea due to primary tongue base closure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON43717

Source
ToetsingOnline

Brief title
REV 002 Observational study

Condition

- Other condition

Synonym
"airway breathing obstruction during sleep" and "obstructive sleep apnea"

Health condition

obstructive sleep apnea

Research involving

Human

Sponsors and support

Primary sponsor: ReVENT Medical International BV
Source(s) of monetary or material Support: The industry sponsor is ReVENT Medical.

Intervention

Keyword: obstructive sleep apnea, sleep apnea device, sleep disorder, tongue-base obstruction

Outcome measures

Primary outcome

To assess the effectiveness of the ReVENT Sleep Apnea System as measured by the reduction at 3 months, 6 months and 12 months in Apnea-Hypopnea Index (AHI) as compared to the pre-operative AHI (baseline).

Secondary outcome

To evaluate patient perception of benefit as measured by change in daytime sleepiness and sleep-related quality-of-life at 3, 6 and 12 months as compared to baseline.

* Daytime somnolence is assessed using the Epworth Sleepiness Scale (ESS). Scores obtained at 3, 6 and 12 months, are compared to the pre-operative score (baseline)

* Patient sleep-related quality-of-life is assessed using the Functional Outcomes of Sleep questionnaire (FOSQ). Total scores at 3, 6 and 12 months are compared to the pre-operative total score (baseline)

TERTIARY OBJECTIVES:

1. To characterize the patient success rate as determined by Sher criteria,

which is defined as achieving both a 50% reduction from baseline in AHI and a follow-up post-surgical AHI level below 20.

2. To assess effectiveness over the study period using other polysomnography metrics and sleep position assessment21.

3. To assess time to recovery after surgery by measuring pain, swallowing and speech on a 0-10 visual analog scale (VAS) every day for 14 days or until recovery. Pain medication consumption and return to normal diet will be recorded.

4. To evaluate the percentage of patients returning to normal work or normal activities after surgery.

5. To summarize the occurrence of Adverse Events (AE) and Adverse Device Effects (ADE).

Study description

Background summary

The ReVENT Sleep Apnea System is manufactured by ReVENT Medical, Inc. (Newark, California, USA) and distributed in Germany by NMP Neuwirth Medical Products (Obernburg, Germany) and in Switzerland and Belgium by ReVENT Medical International, B.V. In Europe, the ReVENT system received the CE Mark in December 2012 and carries CE mark from LNE/G-MED CE 0459.

This observational study is designed to assess the effectiveness and patient perception of benefit of the ReVENT Sleep Apnea System, a new implantable medical device intended for use in stabilizing the tongue for reduction of the incidence of airway obstructions in patients suffering from Obstructive Sleep Apnea (OSA).

OSA is a condition characterized by repeated upper airway obstruction during sleep, potentially resulting in intermittent hypoxemia and arousals from sleep. The consequences of untreated OSA include sudden death, hypertension, stroke, coronary artery disease and congestive heart failure, non-insulin dependent

diabetes, depressive symptoms and decreased quality of life. OSA has the highest prevalence in the general population of all sleep disorders, affecting approximately 3-7% of the middle-aged male population and 2-5% of middle-aged women.

Recent studies suggest that a majority of patients with OSA have obstruction occurring both at the palate and tongue base.The current standard of care for OSA that addresses both levels of collapse is treatment with continuous positive airway pressure (CPAP). While efficacious, at least 40% of patients are unable to tolerate it. Patients who are unable to use CPAP may consider other options, including surgery. Surgical treatment does not require daily usage of any equipment, thus mitigating the lack of compliance associated with CPAP.

However, to be effective, surgical treatment must address the potential sources of upper airway obstruction; mainly collapse of the soft palate and/or tongue base. Because palate surgery rarely eliminates OSA by itself and because of the well- established importance of the tongue in the pathophysiology of OSA, tongue- directed procedures have developed over the past 10-15 years, including genioglossal advancement, radiofrequency or resection of the tongue, and tongue stabilization. Novel tongue implants have also been reported using tissue anchors and magnets. The combination of palate and tongue surgery has demonstrated improved outcomes over palate surgery or tongue surgery alone.

However, many of the tongue-based procedures may be associated with significant morbidity, typically requiring a 2-3 week recovery period, and risk of serious peri-operative complications. Consequently, there is a clinical need for efficacious and minimally invasive tongue-based procedures, followed by a reasonable recovery and return to work/life for the patient. Traditionally, obstructive sleep apnea surgery has not followed this paradigm. Recovery from palate and hypo-pharyngeal surgery is painful, and time away from work can extend up to 3 weeks.

The ReVENT Sleep Apnea System is a minimally invasive tongue-based procedure to treat OSA that consists of implants and implanter kit. The silicone elastomer implants are intended for permanent implantation in the tongue base and dynamically support the tissue after healing. The implanter kit includes all the tools to enable proper delivery of the implant into the tongue.

The ReVENT Sleep Apnea System has been recently marketed to treat patients diagnosed with OSA due to primary tongue base closure. This observational study aims to answer the need for early evidence-based medicine in order to improve treatment decisions for better patient outcomes.

Study objective

To assess the effectiveness and patient perception of benefit of the ReVENT

Sleep Apnea System in patients diagnosed with Obstructive Sleep Apnea due to primary tongue base closure.

Study design

This study is a prospective, international, multi-center, post-marketing, observational study. After surgery and discharge from the hospital, all patients will be followed for a 12-month period with one required post-operative control visit to be performed 1 week after surgery and a further 3 visits to evaluate clinical outcomes at 3, 6 and 12 months, respectively.

There will be neither additional invasive assessment nor any other burdensome investigation with the patient during the study. All assessments/treatments are standard of care in the individual hospital. All data will be collected via CRFs and a secure data entry system.

The planned duration of the study is 2 years. Patient*s time commitment for the study is approximately 1 year. The study is planned to start with patient enrollment beginning in September 2014 and the last projected study visit is in 2016. Study duration was estimated based on enrollment of up to125 patients at up to 15 centers within one year.

Study burden and risks

Concerning inconvenience and/or discomfort with respect to participation in the research, all examinations are considered standard of care for the evaluation and treatment of obstructive sleep apnea.

Use of the Sleep Apnea System involves potential risks normally associated with the use of any tongue implanted device, including but not limited to, those listed below:
* Difficulty swallowing
* Difficulty speaking
* Erosion of Implant
* Implant aspiration
* Implant rejection
* Implant migration
* Infection
* Local inflammation
* Increased mucous production in the airway
* Increased edema in the area of the implant
* Partial/full extrusion of implant
* Sore or scratchy throat
* Voice/taste change
* Allergic reaction to Implant material
* Foreign body sensation

The potential benefit is stabilizing the tongue for the reduction of the incidence of airway obstructions in patients suffering from Obstructive Sleep Apnea.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patient is 18 years of age or older.
2. Patient diagnosed with Obstructive Sleep Apnea due to primary tongue base closure, which may benefit from the ReVENT Sleep Apnea System as per physician*s judgment within the intended use as described in the approved Instructions for Use.
3. Patient with AHI * 10 and AHI *40 during sleep (at least 80% of apneas and hypopneas must be obstructive and at least 20% sleep time must be supine).
4. Patient with BMI * 32.

5. Patient must have been offered CPAP treatment as per National Guidelines and have refused or failed to continue CPAP.
6. Drug Induced Sleep Endoscopy (DISE) will be performed in each patient to determine the site of upper airway collapse: patients must have tongue-based upper airway closure as defined by the VOTE criteria and without any of the following:
a. complete concentric palatal collapse
b. complete isolated epiglottis collapse (i.e., complete epiglottal collapse which does not involve the tongue or lateral walls collapsing in on it)
c. any other anatomy which in the opinion of the physician is not suited for ReVENT implantation
7. Patient able to complete questionnaires and follow post-operative assessment procedures.
8. Patient able to exercise free informed consent.

Exclusion criteria

1. Patient with prior tongue-based surgery (patient with prior minimally invasive radio-frequency tongue-based procedures can be enrolled, but see below).
2. Uvulopalatopharyngoplasty, soft palate surgery or tonsillectomy or minimally ablation of the tongue within six (6) months of the index procedure.
3. History of mandibular and/or hyoid advancement to treat OSA.
4. Any contraindications as listed in the approved Instructions for Use:
a. Patient with enlarged tonsils (3+ and 4+)
b. Patient with anatomy of the oral cavity or tongue unable to accommodate the implant
c. Patient with significant rhinitis/nasal obstruction
d. Patient with history of or ongoing diagnosis of dysphagia
5. Other sleep-related conditions such as Restless Leg Syndrome, REM Behavior Disorder, insomnia or any neuromuscular disease affecting the tongue.
6. Any patient with a history of substance abuse who cannot discontinue alcohol use for 24 hours prior to surgery.
7. Patient with Diabetes type I.
8. Any condition which in the judgment of the investigator would prevent the patient from completing the study.
9. Existing or planned pregnancy during the course of the study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2015
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	18-11-2015
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	15-01-2016
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	31-08-2016
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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
ClinicalTrials.gov	NCT02180815
CCMO	NL54483.048.15