The use of nasal airway stent (Nastent R) in patients with sleep-disordered breathing (SDB) including snoring and/or obstructive sleep apnea (OSA).

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Study aimsThe aim of the current study is to assess the effect of a nasal airway stent (Nastent R) as a treatment modality in patients with snoring and/or OSA. Hypothesis Nastent R, a distally perforated soft silicon nasal tube, is a mechanical...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50116

Source
ToetsingOnline

Brief title
NASTENT trial

Condition

- Other condition

Synonym
Sleep apnea, Snoring

Health condition

obstructief slaapapneu

Research involving

Human

Sponsors and support

Primary sponsor: Nastent, inc
Source(s) of monetary or material Support: Mudita B.V.

Intervention

Keyword: Nasal airway stent, Obstructive Sleep Apnea, Sleep-disordered breathing

Outcome measures

Primary outcome

Assessment of the efficacy of Nastent R in treatment of snoring and/or OSA by use of the RDI.

Secondary outcome

Epworth sleepiness scale score (ESS), Mean SaO2 (SaO2), AHI, ODI (oxygen desaturation index), VAS (visual analogue scale) for snoring as reported by the partner and evaluation of symptoms.

Study description

Background summary

Within the spectrum of sleep-disordered breathing (SDB), obstructive sleep apnea (OSA) is highly prevalent.[1] OSA is caused by recurring collapse of the upper airway during sleep, resulting in complete (apnea) or partial (hypopnea) cessation of airflow.[2] This leads to micro-arousals and sleep fragmentation.[3] OSA severity is expressed by the apnea-hypopnea index (AHI), defined as the number of apneas and hypopneas per hour of sleep.[4] Snoring is common among people who suffer from OSA, however, it can also be present in the non-OSA population (primary snoring) with various reports of its prevalence (15-54%).[5] Besides its considerable impact on social life and its disturbing nature, snoring is associated with several side effects. It has an established link with both patients* and their partners* hyper-somnolence which can lead to more severe consequences such as traffic and work place accidents. Therefore, snoring is indeed a socioeconomic burden.[6] There have been some studies which

claim that snoring can lead to chronic hearing loss, especially in the partner*s ears.[7-9] Snoring can also be a cause for local pharyngeal neurogenic lesions and muscular deformations which can give rise to a progressive upper airway collapsibility and a more severe disease over time.[10] Also, carotid artery atherogenesis and plaque rupture, due to the transmitted local energy from the constant vibrations and the resultant trauma have been associated with snoring.[11]
Several attempts throughout the years have been made for the treatment of primary snoring, including lifestyle changes such as weight reduction, avoidance of nighttime use of caffeine, alcohol and other stimulant substances. Various surgical techniques on different levels of the upper airway from nose to epiglottis have been carried out. In recent years, the use of mandibular advancement devices (MAD) or modified MADs (mandibular obturators), sleep position therapy (SPT) and myofuctional exercise therapies [12] have also been proposed for treatment of snoring.
Pathophysiology of snoring is diverse and therefore, not one treatment suits or is tolerated by all. Bearing in mind that each therapy has limitations, such as the anatomical multilevel nature of snoring in some patients which is a negative predictor for surgical therapies, temporomandibular joint problems and dental issues that can limit the use of MAD, there is always room for novel treatment measures in this area.
In 1972, Walsh and colleagues for the first time tried the insertion of a nasal tube, which was usually used for maintenance of an open airway in burn and trauma patients, as a treatment modality for OSA. They reported good results with a reduction in arousals and hyper-somnolence.[13] Over the years various groups of researchers have tried different methods of using a form of stent or tube for patients with OSA. [14-16] The concept of using a nasal stent has been recently re-visited by OSA experts as another possible treatment option in these patients, in particular for those with a narrow velopharynx. To date, this treatment option has shown good results.[17] Nasal stents can be a simple and readily available treatment option for snoring in patients with SDB.

Study objective

Study aims
The aim of the current study is to assess the effect of a nasal airway stent (Nastent R) as a treatment modality in patients with snoring and/or OSA.
Hypothesis
Nastent R, a distally perforated soft silicon nasal tube, is a mechanical splint that might prevent collapse of the upper airway at multiple levels. It also might reduce the vibrations caused by fluttering of various parts of the upper airway which leads to snoring. Finally, it also might be able to secure a patent upper airway throughout the night.

Study design

Study design
Description study design
- Patients from the ENT department who meet the inclusion criteria will be recruited and informed about the study. Informed consent will be obtained from the patient.
- A baseline portable sleep monitoring evaluation at home using WatchPAT*300 will be carried out.
- After a thorough clinical ENT examination, the right side of the nose (left or right) for each patient will be determined.
- To determine the right size and position, the following protocol is done:
o A Nastent R classic (165mm) is inserted endo-nasally. Throughout the insertion of the stent, the upper airway is being observed under awake fiberoptic nasolaryngoscopy (which is routinely performed during ENT examination of patients with sleep disordered breathing (SDB) in the outpatient clinic) until the end of the nasal stent reaches the base of the tongue and eventually is in contact with the epiglottis. After insertion, a mark is set on the tube to show how much of the tube shaft is still out of the nostril. Based on this marking, the right size and position of the Nastent R can objectively be determined (165mm - protruded part in mm = correct size in mm).
o After length determination, the correct instructions for insertion by the patients themselves will be given in detail and each patient will receive a Nastent R Starter kit (containing 6 different stent sizes, 130, 135, 140, 145, 150 and 155mm). This kit is for patients to gradually increase the sizes each day until they reach the right determined size for them and to get accustomed to the stent by going from small to large to reach their size.
- After this one-week period of using the starter kit, the patient will return to discuss their evaluation on the Nastent R, including an assessment of tolerability and acceptance and to check whether the patient has been able to reach the calculated size by using the starter kit.
o if yes, then a Nastent R classic kit (containing 7 stents (each can be used for two consecutive nights) of the same length (as determined during the previous visit or shorter if the patient has not reached the calculated size) will be prescribed to be used by the patient for 14 nights.
o if not, the reason will be investigated.
Some patients might have gotten a response in the form of resolution of their snoring and apneas on a shorter size than predicted while trying out various sizes of the starter kit. In this case, the shorter size should be prescribed for them.
- During the last night of this 14 days period with the Nastent R inside the nostril, the patient will undergo a control portable sleep monitoring evaluation at home using WatchPAT*300.
- Final visit, after this 14-day period:
To discuss patient acceptance and to decide on the final choice of going ahead with this treatment modality.

Intervention

Study procedures
• After patient inclusion, a baseline portable sleep monitoring at home (WatchPAT*300) for 2 consecutive nights will be performed.
• During the next visit the objective size and position of the stent will be determined under direct visualization using fiberoptic nasolaryngoscopy. Subsequently, the patients will receive a Nastent R Starter kit (containing 6 different stent sizes of Nastent R, 130, 135, 140, 145, 150 and 155mm) to gradually get accustomed to the stent and to find the right size for them.
• During the following consultation, a Nastent R classic kit (containing 7 stents of the same size, each can be used for two consecutive nights) will be given to the patients to be used for 14 consecutive nights.
• During the last two nights of this 14-night period, a follow-up home portable sleep monitoring evaluation (WatchPAT*300) will be performed with Nastent R in situ.
• Afterwards, during the final visit at the outpatient clinic, acceptance of the therapy with Nastent R by the patients will be evaluated, and the decision of whether to continue the therapy and to proceed to the purchase of this product as a long-term treatment for the patient or not, will be made.

Study burden and risks

Benefits and risks assessment, group relatedness
There are little or no risk associated with this study and based on the work of previous researchers, no side effects were observed after long term follow up.
Possible advantages and disadvantages of the therapy
Advantages:
-fast, easy and accessible treatment
-little or no complications
disadvantage
-It might be difficult for some patients to perform the insertion on their own which should be minimized by proper patient education

Incentives
The participants receive no compensation for participating in this study, apart from the fact that they receive the treatment for free during the duration of the study as the Nastent during the study period is provided for free by the company without any additional costs for patients. In addition, there are no extra costs for the patients either.

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

Age > 18
AHI < 20 per hour of sleep
Complaints of socially disturbing snoring by partner
Capable of giving informed consent

Exclusion criteria

- Craniofacial deformities
- Acute nasal trauma, fracture (during past 3 months)
- Nasal valve collapse, synechiae and septal perforation, recurrent epistaxis, recent nasopharyngeal surgery, chronic rhinosinusitis with or without polyposis
- Cerebrospinal fluid leaks
- History of past or current psychiatric disorders (psychotic illness, major depression, or acute anxiety attacks as mentioned by the patient), intellectual disability, memory disorders, seizure disorders, neuromuscular disorders, cardiovascular diseases, coagulopathies (thrombocytopenia< 100/µl), lower respiratory tract disorders.

- Pregnancy or willing to become pregnant
- Excessive alcohol or drug use (>20 alcohol units/week or any use of hard drugs)
- Sleep medication use

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Nastent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-06-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL71812.100.19