

# A Disposable Device NAS to Treat Obstructive Sleep Apnea and Snoring

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## 1. PURPOSE OF THE STUDY

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### a. Brief Summary

The purpose of the research study is to test a new approach for treating patients with snoring and obstructive sleep apnea (OSA). A special device (NAS-nasal stent) appears to be a useful alternative or additive treatment for patients with OSA.

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### b. Objectives

We hope to learn through this study if this device provides a better alternative treatment for obstructive sleep apnea and snoring.

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### c. Rationale for Research in Humans

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## 2. STUDY PROCEDURES

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### a. Procedures

This research study is seeking to enroll up to 30 participants with OSA and snoring. The enrollment will be at Stanford Sleep Medicine Center. The NAS (straight type) supports the soft palate from "collapsing" by supporting it physically, as well as securing the passage of airflow both inside and outside of the tube. Participants in the proposed study will undergo any or all of the following procedures.

After the consent process (30 min), each participant will be asked to complete either paper questionnaires which inquires about his or her demographic information and medical history (Sleep Disorders Questionnaire, 30 min) and level of daytime sleepiness in various situations (Epworth Sleepiness Scale, 5 min) or an electronic questionnaire (Alliance Sleep Questionnaire, 20 min).

Each participant will be asked to submit to an initial evaluation (60 min), which consists of a discussion of the participant's sleep habits and problems, medical history of participant and family, review of systems, medications, education, employment, and personal habits. A general physical examination, including but not limited to examination of the mouth and throat, and measurements of his or her weight and height; circumference of neck, waist, and hip; pulse and respiration rate; and blood pressure.

The participants will undergo two sleep studies: one sleep study at our center prior to using the NAS device (Baseline) and another after 7 days of use of the device at their

homes (Treatment). The participants will wear the NAS device during the second sleep study.

The sleep study will be conducted in routine fashion, with recording electrodes and equipment attached to the participant to enable monitoring of the electroencephalogram (EEG, C3-A2 and C4- A1, O2-A1 and O1-A2), electro-oculogram (EOG, ROC-A1, LOC-A2), chin and anterior tibialis electromyograms (EMG), heart rate by two-lead electrocardiogram (EKG), snoring intensity (anterior neck microphone), nasal pressure (nasal cannula), oral airflow(thermocouple), thoracic and abdominal movement (inductance plethysmography bands), and oxygen saturation (pulse oximetry). The duration of the application of all of these electrodes and recording devices to the participant is approximately 1.5 hours. The polysomnogram will be scheduled to allow at least 7 hours but no more than 9 hours of time in bed for the participant during the night.

The participants will be provided the following instructions for handling the NAS device:

- Before handling the NAS, wash hands and nails thoroughly with soap. Make sure to thoroughly rinse off the soap as well.
- Check NAS package carefully for breakage on the package. In case of breakage, do not use and contact the clinical research staff.
- Check right or left nostril for intended insertion
- Open NAS package, and take out NAS device.
- Insert the tube to the appropriate side and slide NAS device slowly into the nasal airway.
- Clip the stopper on to the nasal septum / bridge to secure the device.
- Open the mouth in front of a mirror; check that there is the tip of the NAS device showing 3mm from the soft palate.
- Go to sleep with the NAS applied.
- Remove the NAS through nose and dispose once awake.
- Limit use of this device to a maximum of 10 hours. Always dispose after use, and do not re-use. Use within six months.

Participants will have the option to receive the nasal device after the second sleep study. The patient will be allowed to receive complimentary nasal stents until the time the device becomes commercially available. During this time, each participant will be asked to complete and submit the Epworth Sleepiness Scale every three months.

-Close out visit

After completion of the first sleep study (baseline) and second sleep study (treatment), subject will be asked to come back for a follow-up visit to discuss the results of his/her sleep studies with the study doctor, Dr. Kushida. During this visit, the study doctor or research coordinator will ask the subject to place the nasal stent into his/her nostril, and the PI or research coordinator will then take pictures of the back of the subject's mouth, where the nasal stent should be resting. Subject's face will not be included in the photos. If after meeting with the study doctor and the subject would like to try the nasal stent in a different size, the subject may have a repeat treatment PSG.

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**b. Procedure Risks**

The above procedures are in clinical use at our center. We are taking all necessary precautions for any risk that may occur in this clinical study.

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**c. Use of Deception in the Study**

Not Applicable

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**d. Use of Audio and Video Recordings**

Participants will be videotaped during the sleep study as per our usual sleep clinic protocol. The videotapes will be kept for 7 years and then destroyed.

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**e. Alternative Procedures or Courses of Treatment**

Alternative treatments for obstructive sleep apnea will be discussed with the participant, including continuous positive airway pressure (CPAP), upper airway surgery, and oral appliance therapy. There are risks/benefits to all these alternative treatments that will be discussed with the participants; these are standard of care treatments.

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**f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?**

Yes

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**g. Study Endpoint(s)**

The study will end after 30 participants are completed.

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**3. BACKGROUND**

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**a. Past Experimental and/or Clinical Findings**

Nasal airway stents have been tried in sample populations with mixed results. The sponsor of the proposed study has developed several versions of their device, of which the device for the proposed study appears to be the most promising as tested in a few subjects by the sponsor in an internal study.

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**b. Findings from Past Animal Experiments**

Not Applicable

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**4. RADIOISOTOPES OR RADIATION MACHINES**

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**a. Standard of Care (SOC) Procedures**

Identify Week/Month of Study	Name of Exam	Identify if SOC or Research
NA	NA	NA

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**b. Radioisotopes**

**i. Radionuclide(s) and chemical form(s)**

NA

- ii. Total number of times the radioisotope and activity will be administered (mCi) and the route of administration for a typical study participant

NA

- iii. If not FDA approved: dosimetry information and source documents (package insert, Medical Internal Radiation Dose [MIRD] calculation, and peer reviewed literature)

NA

**c. Radiation Machines – Diagnostic Procedures**

- i. Examination description (well-established procedures)

NA

- ii. Total number of times each procedure will be performed (typical study participant)

NA

- iii. Setup and techniques to support dose modeling

NA

- iv. FDA status of the machine and information on dose modeling (if procedure is not well-established)

NA

**d. Radiation Machines – Therapeutic Procedures**

- i. Area treated, dose per fraction/number of fractions, performed as part of normal clinical management or due to research participation (well-established procedures)

NA

- ii. FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions (if procedure is not well-established)

NA

**5. DEVICES USED IN THE STUDY**

**a. Investigational Devices (Including Commercial Devices Used Off-Label)**

<b>Investigational Device 1</b>	
Name:	Nasal Airway Stent
Description:	The Nasal Airway Stent (NAS) is inserted into the nose and serves as a mechanical splint to prop open the upper airway.
Significant Risk? (Y/N)	No
Rationale for Non-Significant Risk	Device does not provide for any significant risk. The device is extremely soft and flexible and would be highly unlikely to cause any problems with the soft palate, throat, and/or upper airway.

**b. IDE-Exempt Devices**

<b>IND-Exempt Device 1</b>	
Name:	NA
Description:	NA

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## 6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

### a. Investigational Drugs, Biologics, Reagents, or Chemicals

<b>Investigational Product 1</b>	
Name:	NA
Dosage:	NA
Administration Route:	NA

### b. Commercial Drugs, Biologics, Reagents, or Chemicals

<b>Commercial Product 1</b>	
Name:	NA
Dosage:	NA
Administration Route	NA
New and different use? (Y/N)	NA

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## 7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

Not Applicable

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## 8. PARTICIPANT POPULATION

### a. Planned Enrollment

Our plan is to enroll 30 patients for the NAS study at Stanford. Stanford will be the only site. The population will be 18 years of age and older with snoring and obstructive sleep apnea and exclusion criteria of adults with body mass index (BMI) greater than 30 kg/m<sup>2</sup>.

### b. Age, Gender, and Ethnic Background

Age range is 18 years and older. There are no gender or ethnic background specific criteria.

### c. Vulnerable Populations

- No children will be asked to participate in the study.
- Pregnant women, homeless and economically disadvantaged people will be excluded.
- Persons who are not able to comprehend or understand English.
- Persons who are unable to follow instructions will be excluded.
- Persons with body mass index greater than 30 kg/m<sup>2</sup> will be excluded.

### d. Rationale for Exclusion of Certain Populations

No children will be included in the study, since standard-of-care treatment for sleep disorder management in children is less well defined and standardized than that of adults.

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**e. Stanford Populations**

Laboratory personnel, employees, and/or students will not be excluded from the study, since they will be part of our normal clinic population. No specific number or share of laboratory personnel, employees, and/or students can be part of the study.

Those participants in this research study will also be eligible for the standard study cooperation fee of \$700 and the option of receiving nasal stents after their second sleep study.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

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**f. Healthy Volunteers**

Not Applicable

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**g. Recruitment Details**

Potential participants will be recruited from the Stanford Sleep Medicine Center clinic population as identified via chart review by the research staff. During their clinic visit, only someone with a treating relationship will initially approach the potential subject and, after they have indicated that they are interested in more information about the study, they will contact the research staff or agree to allow their physician to provide their contact information to the research personnel.

In addition, recruitment flyers will be posted in local businesses, as well as running a subject recruitment newspaper ad to obtain subjects outside of the Stanford Sleep Medicine Center clinic population. The phone number and email address of the research coordinator will be on the ads for the interested participant to contact.

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**h. Eligibility Criteria**

**i. Inclusion Criteria**

The population under study will be clinical outpatients 18 years of age or older with symptoms of obstructive sleep apnea and snoring, and with body mass index less than 30 kg/m<sup>2</sup>.

**ii. Exclusion Criteria**

Children, pregnant women, homeless, economically disadvantaged individuals, and those who are unable to comprehend or understand English, or follow instructions will be excluded. Persons with body mass index greater than 30 kg/m<sup>2</sup> will also be excluded.

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**i. Screening Procedures**

Patients at age over 18 will be screened. Clinical outpatients will be recruited from our normal clinic population. No telephone screening will be performed. In addition, flyers will be posted to recruit subjects outside of our normal clinic population.

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**j. Participation in Multiple Protocols**

Our research team will ask this question, and this question will be on our informed consent form. Patients will be given the choice as to whether they want to participate in this study if they are already enrolled in another study.

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**k. Payments to Participants**

The patient will be paid to participate in this research study. It is a cooperation fee of \$700. The payments will be prorated based on the length of participation. Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. Patients may need to provide their social security number to receive payment.

Participants will have the option to receive the nasal device after the second sleep study. The participant will be allowed to receive complimentary nasal stents until the time the device becomes commercially available.

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**l. Costs to Participants**

There is no cost for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits. The study will pay for those services, supplies, procedures, and care associated with the study that are not a part of routine medical care. The patient will be responsible for any co-payments and/or deductibles as required by your insurance.

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**m. Planned Duration of the Study**

The consenting time will take about 15 minutes.

This research study is expected to last approximately one year. The active participation is up to a year. The time for the sleep questions will be about 30 minutes - the sleepiness scale will take about 5 minutes and the electronic questionnaire will take approx. 20 Min. The limit use of this device is a maximum of 10 hours - every night throughout the whole night for 7 days. At baseline and day 8 the patient will be requested to have sleep studies (without the NAS at baseline and while wearing the NAS at day 8).

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**9. RISKS**

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**a. Potential Risks**

i. Investigational devices

If you insert the NAS into the nostril there can be a little nose bleeding because of the damage of the mucous membrane while inserting the NAS device.

There may be some soreness and swelling due to the pressure of the device.

ii. Investigational drugs

Not Applicable

iii. Commercially available drugs, biologics, reagents or chemicals

Commercially available drugs will be used as part of normal sleep disorder treatment. This is not a clinical trial to test medications, so routine medications for the treatment of sleep disorders will be prescribed by the subject's physician as part of their clinical care only.

iv. Procedures

Insertion of the NAS tube to the appropriate side of the nostril.

v. Radioisotopes/radiation-producing machines

Not Applicable

vi. Physical well-being

There can be a little nose bleeding because of the damage of the mucous membrane.

There may be some soreness and swelling due to the pressure of the device.

vii. Psychological well-being

No appreciable risks

viii. Economic well-being

No appreciable risks

ix. Social well-being

No appreciable risks

x. Overall evaluation of risk

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

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**b. International Research Risk Procedures**

Not Applicable

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**c. Procedures to Minimize Risk**

This is a low-risk study, given that the participants will have procedures described above that are part of normal routine medical care.

Protections Against Risks

Treatment: We will have close monitoring of the participants while they are on treatment, including regularly scheduled visits to our center to maintain safety and adherence.

Testing Information: We will keep all of the information collected about the participants in locked files at our center. For computerized data, the data will be stored in password-protected computers at our center.

Further, staff will have completed human subjects training.



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**d. Study Conclusion**

The study will terminate when we have successfully enrolled 30 patients for the NAS study.

The Protocol Director will be monitoring all safety data from Stanford participants, and will determine if it remains safe for a subject to continue. A subject would be discontinued from the protocol at any time if it is determined that subject safety is at risk. The protocol director and/or study coordinator will be reachable by cell phone 24/7 by subjects.

Regarding an adverse/unexpected event, the lab personnel typically become aware of the event directly from the participant or the participant's healthcare provider. Upon becoming aware of an adverse event, the principal investigator should assess whether the adverse event represents an unanticipated problem:

1. unexpected;
2. related or possibly related to participation in the research; and
3. serious or otherwise one that suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

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**e. Data Safety Monitoring Plan (DSMC)**

- i. Data and/or events subject to review

Data Collected From the Participant. Data from forms, questionnaires, and interviews will be entered into a secure, password-protected web portal. All data will also be collected and transferred in compliance with the Health Insurance Portability and Accountability Act (HIPAA).

- ii. Person(s) responsible for Data and Safety Monitoring

The protocol director

- iii. Frequency of DSMB meetings

Not Applicable

- iv. Specific triggers or stopping rules

Within 24 hours of learning of a death, or within 5 days of learning of an unanticipated problem involving risks to participants or others.

- v. DSMB Reporting

Not Applicable

- vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Not Applicable

- vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

Not Applicable

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**f. Risks to Special Populations**

Not Applicable

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**10. BENEFITS**

Study participants will not receive direct benefit; however future sleep medicine patients may benefit. This information about NAS (nasal stent) appears to be a useful alternative or additive treatment for patients with OSA. We hope to gain through this study if this new device provides a better or alternative treatment of OSA.

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**11. PRIVACY AND CONFIDENTIALITY**

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.