

THN

Sleep Therapy Study


INFORMATION FOR PARTICIPANTS

Caution: Investigational device. Limited by United States law to investigational use.

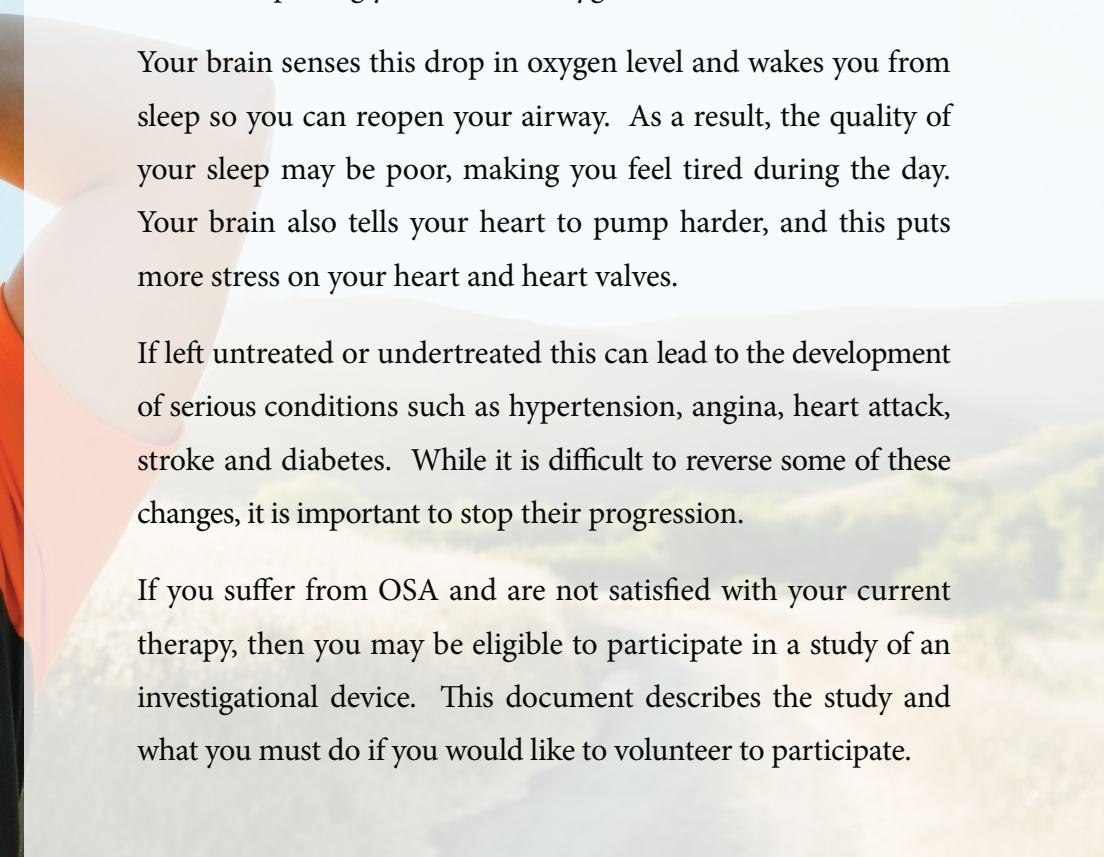


IMTHERA





Obstructive sleep apnea (OSA) is a very serious condition. It occurs when the muscles in your airway relax during sleep, causing your airway to narrow or close as you breathe in, and as a result, depriving your brain of oxygen.



Your brain senses this drop in oxygen level and wakes you from sleep so you can reopen your airway. As a result, the quality of your sleep may be poor, making you feel tired during the day. Your brain also tells your heart to pump harder, and this puts more stress on your heart and heart valves.

If left untreated or undertreated this can lead to the development of serious conditions such as hypertension, angina, heart attack, stroke and diabetes. While it is difficult to reverse some of these changes, it is important to stop their progression.

If you suffer from OSA and are not satisfied with your current therapy, then you may be eligible to participate in a study of an investigational device. This document describes the study and what you must do if you would like to volunteer to participate.

About the THN Clinical Study

The THN™ (Targeted Hypoglossal Neurostimulation) Clinical Study will evaluate the safety and efficacy of hypoglossal neurostimulation in patients with moderate to severe obstructive sleep apnea (OSA) who have been unable or unwilling to use continuous positive airway pressure (CPAP) therapy. Stimulation of the hypoglossal nerve will be provided by a surgically implanted medical device called the aura6000® THN Sleep Therapy System.

You may be able to participate in this study if you

- Have been diagnosed with obstructive sleep apnea with an apnea hypopnea index (AHI) ≥ 20
- Are over 18 years old
- Have a body mass index (BMI) less than or equal to 35
- Are open to considering a surgical option for your OSA
- Are not currently implanted with another active implantable device, e.g. pacemaker, implantable defibrillator, etc.
- Meet the other study inclusion/exclusion criteria
- Are available for follow-up visits at the study site for at least 5 years

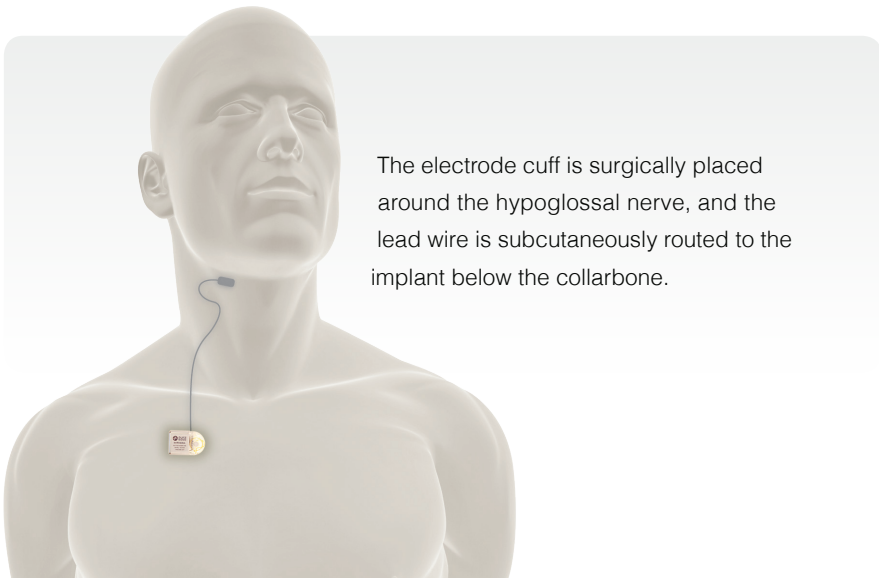
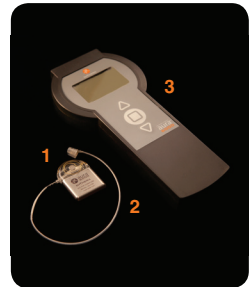
If you are interested in this study, the potential risks and benefits will be thoroughly explained, and you will have the opportunity to discuss participation both with the research staff and your family before volunteering. If selected to participate, you will receive the device, the surgical procedure, and study-related follow-up care free of charge. If you would like more information, or would like to take the next step, visit the THNStudy.com website.

What Is THN Therapy?

Targeted Hypoglossal Neurostimulation (THN) sleep therapy uses pulses of current from an implanted device to stimulate the nerves that control the muscles of the tongue. The stimulation is intended to reduce apneas and hypopneas by increasing the tone of these muscles during sleep, and thereby reduce the number of times that your airway narrows or closes when you sleep.

A THN system looks and operates much like a cardiac pacemaker— except that instead of sending pulses to the heart, it sends pulses to the hypoglossal nerve in the neck. A THN system has the following parts:

- 1 Implant** A small metal case containing a rechargeable battery and electronics that generates pulses which stimulate the nerve
- 2 Lead with electrode cuff** A cable with electrodes that carry pulses of current from the neurostimulator to the nerve
- 3 Remote** A device similar to a TV remote control that you will use to start, stop or pause, and charge the implant as necessary



The electrode cuff is surgically placed around the hypoglossal nerve, and the lead wire is subcutaneously routed to the implant below the collarbone.

How Does The Study Work?

The objective of the THN Clinical Study is to collect data to determine whether or not hypoglossal neurostimulation delivered by the aura6000 System is safe and effective. To accomplish this, the THN Study has been designed as a randomized controlled study.



The study is “controlled” meaning that there are two groups, one which will begin to receive neurostimulation approximately one month after surgery (the “Treatment Group”), and one which will wait until three months later (the “Control Group”). The study is “randomized” meaning that participants will be randomly

assigned to the groups. After the control period, those who were in the control group will also begin to receive neurostimulation. This study design is necessary to properly evaluate the safety and efficacy of the system.

Every study participant will make the following visits to the study doctors:

Four screening visits The first of these visits is with a sleep doctor. It takes about 2 hours and requires participants to undergo a physical examination, and to complete some questionnaires and other forms. The second visit is with a surgeon to see if there are any reasons why you should not undergo the surgery. It takes about an hour. The third and fourth visits are overnight polysomnographies (PSGs) at a sleep laboratory.

Surgery The surgical procedure takes about 60 minutes. Participants will check into the hospital on the day of surgery and may or may not stay overnight at the hospital.

Randomization About 2 weeks after surgery, participants will be randomly placed into either the Treatment Group or the Control Group. Participants in the Treatment Group will have another PSG about 30 days after surgery, at which time their stimulation will be started. Participants in the control group will wait until Month 4 before starting stimulation.

Follow Up In the first year after surgery, the study site will contact participants regularly to monitor their progress, and participants will make at least 2 visits to the study center and spend at least 6 nights at the sleep laboratory. After the first year, participants will visit the study center and have a PSG once per year for four more years.

SCREENING	SURGERY	FOLLOW UP		
Baseline visit 1-2 hours Surgeon visit 1 hour PSG #1 Overnight PSG #2 Overnight	Surgery 1 hour	Timing	Treatment Group	Control Group
		< 2 weeks	Randomization	
		2 weeks	Wound check	
		Month 1	PSG	
		Month 2	PSG + 1/2 hr	1/2 hr
		Month 3	PSG	
		Month 4	PSG	PSG
		Month 4 + 1 day		PSG
		Month 5		PSG
		Month 6		PSG
		Month 8	Phone call	Phone call
		Month 10	PSG	Phone call
		Month 12	PSG + 1 hr	
		Month 13		PSG
		Month 15		PSG + 1 hr
		Month 24, 36, 48, 60		PSG + ½ hour

Frequently Asked Questions

What is a Clinical Study?

A clinical study involves treating and watching a group of volunteers to see whether or not a particular technique is a safe and effective way of treating a certain condition. ImThera Medical, the study's sponsor, has received approval from the FDA (United States Food and Drug Administration) for this clinical study to evaluate the aura6000 system for the treatment of obstructive sleep apnea.

What is being studied?

This study is investigating whether or not stimulating the hypoglossal nerve with an implanted neurostimulation system called the aura6000 Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy System is safe and effective for treating obstructive sleep apnea.

What are the benefits of participating in this study?

If you are selected to participate in this study, you will:

- Work with a sleep doctor and team of healthcare professionals that have experience with moderate to severe obstructive sleep apnea
- Contribute to the understanding of hypoglossal neurostimulation for obstructive sleep apnea
- Possibly help yourself and others by increasing the medical community's knowledge about obstructive sleep apnea
- Receive study-related care at no cost

What are the risks of participating in a clinical study?

Clinical studies are designed to evaluate the safety and efficacy of investigational drugs and devices. All clinical studies involve some risk.

All potential participants will be given an informed consent form which provides detailed information about the study procedures, risks, and potential benefits. The doctors and nurses expect you to have questions, and they are available at each center to answer all of your questions before you make your decision about whether or not to participate in the study.

Will my insurance pay for this?

The device, surgical procedure, and study-related follow-up care will be provided at no cost¹.

How are participants selected for this study?

The THN study has specific rules about who can participate and what procedures must be followed during the study. The doctors and nurses at the clinical study centers are familiar with these rules and will use them to determine if you meet the criteria to participate.

What is a hypoglossal nerve?

A hypoglossal nerve (12th cranial nerve) is a nerve that supplies the muscles of the tongue with signals from the brain which enable it to move. You have two hypoglossal nerves—one on the left and one on the right side of your neck.

What is the aura6000 THN Sleep Therapy System?

The aura6000 THN System consists of two implantable parts—an implant and a lead; and two parts which are not implanted—a programmer and a remote. The implant is a rechargeable battery-powered computer that generates mild pulses of electrical current; and the lead is a cable that carries those pulses to the hypoglossal nerve. The programmer is used by a doctor or nurse to adjust and customize the therapy to your needs. You will be given a remote to start, stop or pause therapy, and to charge the implant.

How does the aura6000 THN System work?

The system looks and operates much like a pacemaker, except that instead of sending pulses of current to the heart, it sends pulses to the hypoglossal nerve which cause some of the muscles of the tongue to stiffen, increasing the opening in the upper airway.

Can you describe the surgery?

The surgery will take about one hour and you will be asleep (general anesthesia). The surgeon will make two approximately 2 inch long incisions—one under your jawbone to place the lead around your hypoglossal nerve; and one on your chest to hold the implant.

How long is the recovery time after surgery?

Depending upon a variety of factors, you may be able to go home the same day that you have your surgery, or your doctor may want to keep you overnight. Either way, you are likely to eat a regular meal within a few hours of surgery.

Over two to four weeks, your body will form scar tissue around your implant and lead, which will help to keep them in place. Until that time, you should avoid activities, and avoid extreme head or neck movements, that could change the position of the implanted components.

Are there risks related to the surgery?

Yes. All surgeries carry risks, such as infection, bleeding, and complications from anesthesia. Some of the risks depend upon your medical history and general health, so it is important that you discuss this question with your surgeon, as he can properly assess the risks and the benefits.

What does stimulation feel like?

Most people report feeling a tingling sensation in their tongue muscles when the stimulation is on—some people report that they don't feel anything. The stimulation will be adjusted so that it is not painful or uncomfortable, and so that it will not wake you from your sleep.

Will people be able to tell that I have an aura6000 system implanted in me?

Probably not. The system is totally implanted meaning that there are no wires or other parts that protrude through the skin. The surgeon will make two incisions to implant the neurostimulator and lead. The incision scars may be visible. Talk to your surgeon about what to expect.

Do I have to wear anything while I sleep with the aura6000 System?

No. The aura6000 system is totally implanted. There are no masks, hoses, mouthpieces, or anything else connected to you. You will be given a remote (like a TV remote control) to turn the system on at night. The remote will sit on your bedside table so that you can turn the system off when you wake up in the morning.

Will this reduce my snoring?

Possibly. THN Therapy is not a therapy for snoring, but it may help to reduce your snoring. THN Therapy works by stiffening the tissues in the upper airway, and some of these tissues may be responsible for some of your snoring.

What will I have to do if I participate in the THN study?

Before you can be accepted in the THN study, you will have to be examined by the clinical study team and spend two nights in a sleep laboratory to determine if you meet the requirements to participate in this study. You will also have to be examined by a surgeon to see if there is any reason why you should not have the surgery.

If you are accepted into the study, you will undergo surgery to receive a hypoglossal neurostimulation system. After surgery, a study team member will be assigned to contact you periodically between study visits to guide you through the study. After surgery, you will visit your study site at least 2 times in the first year, and then once per year for the next four years. You will also spend six or more nights in a sleep laboratory during the first year after surgery and then one night per year for the next four years.

WHO IS IMTHERA MEDICAL?

ImThera Medical is a San Diego, California based medical device company. The company's mission is to help OSA patients live longer and enjoy better lives while substantially reducing the health care costs related to the serious complications associated with obstructive sleep apnea. ImThera designed and manufactures the aura6000 Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy System that is being implanted in the THN Study. More information about the company can be found online at www.ImTheraMedical.com.

For more information or to take the next step, visit
www.THNStudy.com

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