Auricular Neuromodulation and Surgical Conditions During Functional Endoscopic Sinus Surgery

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STUDY INFORMATION:

Study Title: Auricular Neuromodulation and Surgical Conditions During Functional Endoscopic Sinus Surgery

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital

Lead Researcher (Principal Investigator): Daniel Katz, MD

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SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to determine if a device called the Sparrow Ascent can improve the operating environment for the surgeon during your surgery that you already have scheduled on your sinuses. The device is FDA cleared for a different condition but has not been studied for this use. The investigators believe that using this device will decrease the amount of bleeding you have during your surgery which may lead to better operating conditions. If you participate in this study you will be randomly assigned (like flipping a coin) to having the device or not.

If you choose to take part, you will be asked to:

- Allow access to your medical records to verify your current medical status, medical history and medications
- Place the device by your ear in the area before going into the operating room
- Remove the device before you enter the operating room
- Reapply the device when you are in the post anesthesia care unit after surgery is complete
- Call you the day after your surgery to check in with you
- There are no costs associated with this study
- There is a potential benefit to you by having better surgical conditions, but this is not proven
- This device is ONLY being offered to those participating in the study
- There is no payment to you for participating in the study

- This study will not impact any other aspect of your medical care

If you choose to take part, the main risks to you are:

- Loss of private information
- Skin irritation at the site of the device placement
- Some patients experience a slight tingling sensation when the device is on.

You may benefit from taking part in this research. Some potential benefits are: better operating conditions for your surgeon, such that they can see better with less blood where they are operating, less blood loss during your surgery.

Instead of taking part in this research, you may choose to go forward with the standard surgical procedure. However, the only way to access this device is to participate in the study.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are having functional endoscopic sinus surgery, often referred to as FESS.

Your participation in this research study is expected to last 2 days.

There are 20 people expected to take part in this research study at Mount Sinai Hospital.

Funds for conducting this research study are provided by Mount Sinai

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to take part in this research study, here is what may be involved:

- After signing the consent form, the study team will quickly verify your records to ensure that you qualify for the study
- After verification, your surgery will proceed as normal, but with one exception, discussed below
- Before you enter the operating room, a device will be placed on your ear. The device is called the Sparrow Ascent. It has two electrodes that provide something called “vagal nerve stimulation”. The vagus nerve, which is the target of the device, is a nerve in the body that serves many functions,

and the device provides an electric stimulus along that nerve. One of the roles of the vagus nerve is to activate part of the blood called platelets that make the blood clot better. The device has been used in other contexts including opiate use disorder, anxiety, and others. It is also currently under investigation for other bleeding disorders including Von Willebrand Disease and for women who have excessive bleeding during menstruation. The device has been used in opiate use disorder and anxiety for along time without any known side effects. The stimulation applied is the same as what has been used for opiate use disorder and will be applied only during the surgery. In this case it is a shorter duration that is used for opiate use disorder.

- Once the device is placed by your ear, you will be randomized (like flipping a coin meaning only half the participants get the stimulation) to either have the device turned on or off.
- The device will be left on for 30 minutes and will be removed before entering the OR.
- After the surgery is complete, the device will be reapplied in the in the post anesthesia care unit for 30 more minutes.
- The following day a member of the team will call you to check in. No formal questionnaires or interviews are being administered; we only want to ensure you have no irritation on your skin where the device was applied.
- All research activities will take place at Mount Sinai except for your follow up phone call.
- Because this research study involves the use of an investigational medical device, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to or whether or not the device is turned on. It will be by chance, like flipping a coin. You will have a(n) equal chance of having the device turned on. Neither you nor the Lead Researcher or your own doctor will know whether the device was turned on or not. If there is an emergency, they can get this information.

USE OF YOUR DATA AND/OR SAMPLES:

The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

- *Access your medical records*
- *Apply and remove the device in the room before the operating room*
- *Apply and remove the device in the recovery room*
- *Call you the next day*

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this study. Being in this study will not cost you anything extra.

POSSIBLE BENEFITS:

There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Possible benefits to you include:

- Less bleeding during your surgery
- Better operating conditions for your surgery
- Lower postoperative pain scores

POSSIBLE RISKS AND DISCOMFORTS:

- Skin irritation at the site of the electrode placement which is by the ear.
- A tingling sensation in your body is sometimes felt with this device
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- In addition to these risks, this research study may hurt you in ways that are not known. The unknown risks could be minor.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you.
Instead of being in this research study, your choices may include:

- *Proceed with your standard surgery.*
- *This device is ONLY being offered to those who are involved in the study.*

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher. Their contact information is listed at the beginning of this consent form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 212-241-7475

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, phone number, medical record number.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the

following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The FDA

In all disclosures outside of Mount Sinai, you will not be identified by name or medical record number unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time [required if used for FDA documentation purposes]

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when participant is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time