Utilization of a Microcurrent Device for Postoperative Pain Following Functional Endoscopic Sinus Surgery: a Randomized Controlled Trial
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STUDY INFORMATION:

Study Title: Utilization of a Microcurrent Device for Postoperative Pain Following Functional Endoscopic Sinus Surgery: A Randomized Controlled Trial

Study site(s): Mount Sinai Doctors - East 85th Street, Mount Sinai Hospital, Mount Sinai Union Square, New York Eye & Ear Infirmary of Mount Sinai

Principal Investigator (Lead Researcher):

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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 see whether daily use of a device applied to the forehead and cheeks, called a microcurrent neuromodulation device, will decrease the pain experienced by patients in the days following functional nasal and endoscopic sinus surgery versus a placebo device that is identical to the study device, but does not emit an electrical current. Current methods for pain management after sinus surgery involve medications such as acetaminophen and opioids, which can have short- and long-term risks. This study will see if the use of this device can provide relief of pain, while allowing patients to decrease their need for these medications. This device is an investigational device, meaning it has not been approved by the Federal Drug Administration.

If you choose to participate, you will be asked to attend all of your scheduled appointments before and after surgery. At the first appointment before surgery, you will be shown how to use the device by the research staff. You will receive the device after your surgery. You will be asked to use the study device at home covering your first two (2) post-operation visits for a minimum of 2 weeks following your surgery. During that time, you will be asked to record your pain level before and after use of the device, as well

as any pain medication that you used. You will continue to receive all standard medical care as determined by your surgeon.

The main risks to you if you choose to participate are all risks that are normally associated with sinus surgery, including bleeding, infection, and damage to nearby structures during the procedure. Other surgical risks will be explained to you by your surgeon during a separate consent process for surgery.

Other risks associated with the use of the study device can include redness and irritation of skin at the site of device usage. In addition, some participants may be sensitive to or feel uncomfortable with the tingling/vibrating sensation generated by the device.

You may also benefit from participation in this research if the device is effective at controlling your pain and you require fewer opioids or other pain medication.

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 will be scheduled for functional nasal surgery or endoscopy sinus surgery in treatment of chronic rhinosinusitis, and are otherwise healthy, with no chronic pain requiring the use of opioid medication.

Your participation in this research study is expected to last for a minimum of two (2) weeks after your surgery up to no more than 21 days covering your first two (2) post-operation visits.

The number of people expected to take part in this research study at Mount Sinai Health System is 60

There are sixty (60) people expected to take part in this research study at Mount Sinai Doctors Faculty Practice at 85th Street, Mount Sinai Union Square, New York Eye and Ear Infirmary and the Mount Sinai Hospital all within the Mount Sinai Health System.

Funds for conducting this research are provided by TIVIC Health Systems, Inc. The study devices will be provided by the manufacturer, TIVIC health.

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

DESCRIPTION OF WHAT IS INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

All study visits will take place at your surgeon's clinic and at Mount Sinai Hospital on the day of your surgery. After your surgery when you are fully awake, your pain level will be determined to see if you are eligible to participate in the study. You will be given the study device and asked to use it to treat your pain for five minutes. Your pain level will be recorded before and after use of the device.

You will be given a prescription for pain pills after your surgery, which is the normal way that pain is treated following sinus surgery. When you leave the hospital after your surgery, you will be given the study device, charger, a pain diary, and instructions on how to use the device, and a medication diary. You will be asked to use the device 3 times per day (morning, afternoon, and night) for 5 minutes and record your pain rating before treatment and 10 minutes, 2 hours, and 4 hours after treatment.

If you are experiencing pain at other times, you will use the device as needed and record your pain level before and after use as above. You will also be asked to record the total number of pain pills taken every day on the medication diary sheet.

When you come into the office for your first regularly scheduled post-operative visit, you will be asked to bring the study device. You will be asked to use the device before and after your surgeon cleans out your nose and sinuses, which is routinely done after sinus surgery. You will be asked to record your pain level before and after as above.

You will continue to use the study device and record your pain level and medication use after your first post-operative visit. You will bring in the device for your second visit where your surgeon will again clean your nose and sinuses. The study device will be collected from you then, and this will conclude your participation in the study.

The study will require you to record your pain level between visits. The study investigators may contact you via telephone to discuss your participation in the study, and to remind you to bring the necessary materials to post-operative visits. You may also be contacted via email to answer survey questions regarding your experience using the study device.
Because this project involves the use of medications or a medical device, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

Randomization

The study treatment you get will be chosen by chance, like flipping a coin. This involves you being randomly assigned to receive either an active device or a sham device. You will have an equal chance of being given either experimental treatment. 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. Neither you nor the study doctor will know which experimental study treatment you are getting. However, if there is an emergency, they can get this information.

USE OF YOUR DATA

The research team will never use or share your personal information (such as, name, address, date of birth), study data that are collected as part of this study for future research, even if your identity is removed. Your data 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: attending all regularly scheduled visits with your surgeon, using the study device three times a day or as needed, recording pain levels before and after device usage, and recording medication usage.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you a $75 prepaid e-gift card reimbursement at the end of your participation in the study for your time and effort. This $75 e-gift card will be sent via the email address you provide to the study team after you have signed the study consent. Being in this research study will not lead to extra costs to you. The study device will be provided at no cost to you for your use during the duration of your participation in the study.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

It is possible that products may someday be developed with the help of your data and there are no plans to share any profits from such products with you.

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 pain relief after using the device, and a decrease in the need for postoperative medications including opioids and acetaminophen.

POSSIBLE RISKS AND DISCOMFORTS:

Surgical risk:

The risks to the study participants will include all risks in patients normally undergoing surgery for chronic rhinosinusitis. Depending on the nature of the surgical procedure any of the following risks may apply: bleeding, infection, damage to adjacent structures, blood vessels, nerves, and eyes. Loss of function associated with sinus surgery such as effects on smell, sensation of breathing, poor wound healing, aspiration, risks associated with anesthesia, and even death. Standard consent processes apply to all study participants, as they are undergoing treatment for their disease. Participants will be signing a separate clinical consent form, which details these risks in depth.

Risks associated with the study device and/or participation in the study:

- Physical risks: there is a risk of skin burns at the site of the device usage; this is a rarely expected risk. There is a risk that the study device may cause irritation and redness at the site of administration; this risk is also rare, and it has been observed to resolve after stopping usage of the device
- Some participants may experience an uncomfortable sensation of tingling and/or vibration when using the device; this sensation typically resolves shortly after participants stop using the device.
- If you have any type of implant in your head or face, including but not limited to jewelry, metal plating, or cochlear implant, there is a risk of interaction between the device and the implant. As such, you will not be able to participate in the study.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

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. You will still receive standard medical treatment for your pain as determined by your doctor. The choice is totally up to you.

The important risks and possible benefits of these alternatives are listed below:

- By not participating in the study there is a risk you may require more medication to treat your pain after surgery.
- Use of opioid medications: if these medications are used incorrectly, there is a risk of getting addicted. Also, if you take too much at once, or take them with alcohol or certain other drugs, opioids can cause serious harm or even death from overdose.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that you have suffered an injury related to this research as a participant in this study, 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 will be asked to return the study device and study materials at your next routine visit with your surgeon.

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.

If you stop being in the research study, the research team may not remove information they have already placed in the study database, and may continue to use that data as part of this 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.

More possible reasons for removal from the study include adverse reactions to the study device, including but not limited to rash, skin irritation, or burn.

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: 212-731-3297.

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

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.

The company TIVIC health manufactures the study device being tested and has a financial interest that could be affected by the outcome of this research study.

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, telephone number, date of surgery and post-operative visits, e-mail, and medical records number. The researchers will also get information from your medical record at Mount Sinai Hospital Systems.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- 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.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.

- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

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 commercial sponsor- TIVIC health and/or their representative (who will use the results for submissions to the Food and Drug Administration)
- The United States Food and Drug Administration that oversees the use of this investigational device and have to assess it safety, use and effectiveness

In all disclosures outside of Mount Sinai, you will not be identified by [name, social security number, address, telephone number, or any other direct personal identifier] 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 protected health information 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.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

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.

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) 306-5070. 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

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

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