NCT04857281

Non-invasive Vagal Nerve Stimulation (nVNS) for Symptomatic Exacerbation of Nausea in Patients With Gastroparesis and Related Disorders

Date: 04-18-2022

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Non-invasive vagal nerve stimulation (nVNS) for symptomatic exacerbation of nausea in patients with gastroparesis and related disorders

Application No.: IRB00265410

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

If you are a parent or legal guardian of a child who may take part in this study, your permission is required for your child to participate. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

This research is being done to evaluate whether using a non-invasive handheld device (called a gammaCore "nVNS") to deliver electrical stimulation to the vagus nerve will be effective in reducing symptoms of nausea and vomiting, as well as reducing the use of rescue medications.

Participants will be in this study for about 12 weeks, which includes a Screening Period of about 2 weeks, Study Device Period of about 8 weeks, and 2 Follow-up Visits (one at 4 weeks after starting the study device and one at 10 weeks after starting the study device). During the study, you will be asked to complete questionnaires, an electrocardiogram to measure the electrical activity of your heart, and pregnancy tests if you are a woman capable of becoming pregnant. During the Study Device Period, you will have the nVNS available to use when you experience nausea, and you may use rescue medications as needed.

Risks of participating include discomfort, redness and irritation of the skin where the device is used, pain, dizziness, muscle twitching and headaches from using the device. There may or may not be benefits to you from being in this study.

2. Why is this research being done?

Several medications are used to treat gastroparesis and Chronic Unexplained Nausea and Vomit (CUNV); however, the drugs can cause side effects. The vagus nerve plays a key role in regulation of nausea and vomiting, and this research study uses electrical stimulation of the vagus nerve to affect nausea and vomiting symptoms.

This research study will use a handheld non-invasive device called GammaCore, which is applied on the side of the neck and sends gentle, patented mild electrical stimulation through the skin to activate the vagus nerve. This method, called "Non – Invasive Vagus Nerve Stimulation (nVNS)", could provide a more effective and safer alternative to the use of traditional rescue medications.

Are there any investigational drugs/devices/procedures?

Gammacore is approved by the Food and Drug Administration (FDA) for the treatment of migraines and cluster headaches. It is not approved for use in gastroparesis or CUNV. This device is pictured below.

Who can join this study?

People 15 years or older with diagnosis of gastroparesis or CUNV with gastric emptying and ongoing symptoms such as nausea, vomiting, and abdominal pain for at least 3 months without any other obvious cause may join.

A total of 45 patients will be accrued in this project.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Screening visit:

You will be asked to complete a screening period to determine if you are eligible to continue in the study, which may take up to 2 weeks.

You will have an electrocardiogram (EKG), which is the electrical study of your heart. You will be asked to complete a urine pregnancy test and questionnaires to answer regarding your health, medical history and medication use.

You will be asked to keep a daily diary to record any migraines and/or headaches you experience and to record any rescue medications you use each day, which includes the dosage, frequency and number of pills.

If you are found to be eligible for this study, you will be asked to continue with the study below.

Study Device Start Visit:
At this visit, you will receive the gammaCore (nVNS) device (called the study device) and trained in its use. When the nauseas gets bad enough that you feel the need to use a rescue medication, you will be asked to first use the study device on one side of the neck for two 2-minute stimulations and wait fifteen minutes to check if the stimulations work. If the stimulations do not help, you will be asked to do an additional two stimulations and wait for another fifteen minutes. If there is no improvement after the second round of using the device, rescue medication will be used. Rescue medications that will be allowed for this study are ondansetron, promethazine and prochlorperazine. During this time, you will be asked to continue the daily diary to record rescue medication use and any migraines/headaches you experience. nVNS can be used up to, but no more than, 8 times a day. You will have the study device available for 4 weeks.

Follow-up Visits
Week 4 visit
At the end of 4 weeks with the study device, you will be asked to visit the study site to have an EKG (to measure the electrical activity of your heart) a urine pregnancy test and questionnaires. You will be asked to continue with the daily diary for headaches/migraines and rescue medication use.

Week 8 visit
At the end of 4 weeks with the study device, you will be asked to complete questionnaires. You will be asked to continue with the daily diary for headaches/migraines and rescue medication use. After this visit, you will start 2 weeks in which you will not have the study device available.

Week 10 visit
This will be the last visit of the study. We will collect your medical history information, your daily diaries, and ask you about any symptoms or side effects you may have had since the last visit. You will be asked to complete questionnaires.

The biospecimens (such as blood or urine used for the pregnancy test) you provide for this research study will be processed and then immediately discarded. Your samples will be used as part of this research study only and will not be used or distributed for future research.

Will research test results be shared with you?
It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

How long will you be in the study?
You will be in this study for 12 weeks.

4. What happens to data that are collected in the study?

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within Johns Hopkins.

If data are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

nVNS

Side effects observed in less than 2.5% of the participants in other nVNS studies include:

- Discomfort, irritation, and redness at the site of where the device is placed on the skin.
- Local pain in the face, head, or neck area (including toothache)
- Muscle twitching and/or contractions of the face, head, neck area (including facial droop and/or lip pull)
- Headaches and/or migraines.
- Dizziness.
- Tingling, pricking, or a feeling of “pins and needles” on the skin where the device is applied.

These reactions resolved after use of the nVNS device was completed.

Other side effects not seen in previous studies with the nVNS device, but associated with implanted vagal nerve stimulation devices include:

- Tingling, pricking, or a feeling of "pins and needles" on the skin where the device is applied (paresthesia or dysesthesia) lasting beyond the treatment period.
- Fainting (syncope), light-headedness, and/or dizziness.
- Sweating.
- Fatigue, depressed mood.
- Tinnitus (ringing in the ears)
- Diarrhea
- Abnormal heart rhythm

Interviews or questionnaires
You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

Unknown risk
There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

It is unknown whether this research may hurt an embryo or fetus. You will not be able to take part in this study if you are pregnant or nursing.

7. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?

You do not have to join this study. Other options may be discussed with your gastroenterologist including medications to control your gastrointestinal symptoms, gastric electrical stimulator placement, or dietary modifications.

If you do not join, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

No.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
The study coordinator will maintain a list of all participants, each having a unique participant code, along with personally identifiable information, such as your email, name etc. Your de-identified information will be stored in a locked cabinet in the motility clinic at Bayview.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

15. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

16. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Pankaj Jay Pasricha MD at 410-550-6766. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Pankaj Jay Pasricha MD at 410-550-6766 during regular office hours and at 443-613-8152 after hours and on weekends. If this doctor is not available, the operator will page the "on call physician."

17. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

18. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

Signature of Parent/Legal Guardian/Court-Appointed Representative **FOR CHILD PARTICIPANT**	(Print Name)	Date/Time

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

Signature of Parent #2 (Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)	(Print Name)	Date/Time

Signature of Child Participant (optional unless IRB required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time
Signature of Participant	(Print Name)	Date/Time
Signature of Parent/Legal Guardian/Court-Appointed Representative **FOR CHILD PARTICIPANT**	(Print Name)	Date/Time
Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)		Date/Time
Signature of Parent #2 (Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)	(Print Name)	Date/Time
Signature of Child Participant (optional unless IRB required)	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).