Transcutaneous Electroacupuncture for Gastrointestinal Motility Disorder

NCT04349891

October 3, 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: **Transcutaneous Electroacupuncture for Gastrointestinal Motility Disorders**

Application No.: **IRB00247402**

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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.

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 double blinded research is being done to test if the transcutaneous electroacupuncture device (TEA) can reduce the severity of your gastrointestinal (GI) symptoms. This will be compared with a Sham TEA. "Sham" means a procedure that seems like the active TEA procedure, but does not work the same as the active TEA. You will be asked to come 4 to 6 times to the clinic in a period of 10 weeks. During these visits, you will provide a medical history, an electrical study of your stomach, and blood samples. You will be instructed how to use the TEA or Sham TEA device for self-administrated home sessions 2 hours after every meal for 4 weeks, stop for 2 weeks and restart for another 4 weeks.

2. Why is this research being done?

This research is being done to test if the transcutaneous electroacupuncture device (TEA) can reduce the symptoms of gastrointestinal motility disorders such as functional dyspepsia (FD), gastroparesis (GP), and chronic constipation.

FD is associated with upper abdominal discomfort or other symptoms such as pain, early fullness, nausea, vomiting, and abdominal distension. GP, also called a condition of delayed emptying of the stomach, is a disorder in which the stomach takes too long to empty its contents. Normally, the stomach contracts to move food down into the small intestine for digestion. The special nerve, called "vagus" controls the movement of food from the stomach through the digestive tract. GP occurs when this nerve is damaged and the muscles of the stomach and intestines do not work normally. Food then moves slowly or stops moving through the gut. Chronic constipation is a syndrome defined by bowel symptoms, including reduced stool frequency (less than 3 times per week), straining to defecate, hard stools, and the inability to defecate.

Are there any investigational drugs/devices/procedures?
The TEA device used in this study is an electronic device that is programmed by a computer to deliver weak electrical signals to electrodes that are held on areas of the arms and legs with adhesive. The electrodes are used to stimulate points on the body that have been shown in previous studies to improve abdominal symptoms.

The use of TEA in this research study is investigational. The word "investigational" means that TEA is not approved for marketing by the U.S. Food and Drug Administration (FDA).

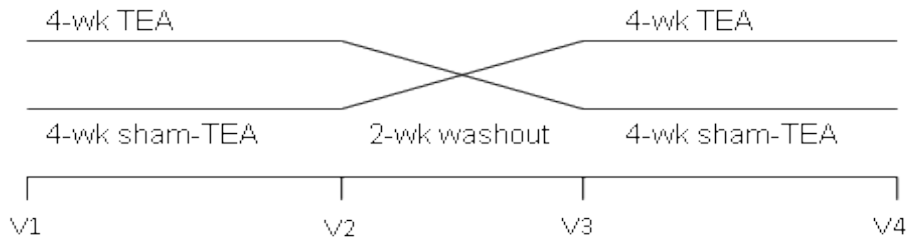
Who can join this study?
People who have been diagnosed with functional dyspepsia, gastroparesis or chronic constipation may join.

How many people will be in this study?
About 120 people will take part in this study. 40 patients with Functional Dyspepsia, 40 patients with gastroparesis, and 40 patients with chronic constipation will be blinded about the treatment regimens and patients who are familiar with the acupoints or meridian will be excluded.

3. What will happen if you join this study?

If it is determined that you meet the criteria to participate in this study and you wish to participate, you will be asked to sign this consent form.

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



Visit 1 (Week 0)

This visit could be conducted over 2-3 different days, as some of the tests need a fasting stage and they are time consuming.

We will accommodate your schedule as much as possible.

Visit 1A
At your first study visit your medical history will be taken and a physical exam will be performed. This exam will include measurements of your weight and vital signs (pulse, blood pressure, and temperature). Women who are able to become pregnant will have urine collected for a pregnancy test. The result of this test must be negative for you to take part in the study.

If you are using insulin for diabetes, please ask the study doctor when you should take your morning dose on the day of your testing. This is because you will be required to fast overnight prior to your study visits.

Questionnaires
You will be asked to fill out a quality of life questionnaire and other questions about your stomach symptoms. You will be asked about the severity of your symptoms, how your symptoms affect your life, and the meals you have eaten.

Visit 1B

EGG Testing
You will have measurements done of the gastric and cardiac nerve (vagus nerve) for 60 minutes before and for 60 minutes after eating the test meal. This is done by an electrogastrogram (EGG). Electrodes will be applied to the skin of your stomach while you are lying down. You may also be asked to wear the TEA device during portions of this test.

Blood Testing
Blood will be drawn at the beginning of EGG/ECG testing and 30 and 60 minutes after the test meal, to test levels of special digestive hormones. About 1 tablespoon of blood will be drawn at each visit. The total blood drawn during this study will be about 4 tablespoons.

TEA or sham TEA Device
You will be randomly assigned (by chance, like the flip of a coin) to either the TEA or Sham TEA group. You will not know the group to which you are assigned. You will be trained on the placement of the TEA or Sham TEA electrodes. You will be taught where to place the electrodes, how to operate the stimulator, the amount of time to wear the TEA or Sham TEA, and how to store the equipment. You will use the TEA or Sham TEA device at home for 2 hours after each meal. You will also wear the TEA or Sham TEA device during testing at Visits 2 and 4.

Visit 1 will last 1.5-2 hours.

Weeks 1, 2 and 3
You will not have a study visit on these weeks. However, you will be asked to wear the TEA or Sham TEA as instructed and complete questionnaires at home and bring them to the study site at your next study visit.
Week 4 (Visit 2)

Visit 2 will be at the study site and you will complete:
- Symptom and quality of life questionnaires
- EGG measurement test
- Blood draw for GI hormones
- TEA or Sham TEA use and testing

This visit could last up to 7 hours.

2 weeks of Wash out period.
You will stop using TEA or Sham TEA for 2 weeks after visit 2.

Week 6 (Visit 3)
Visit 3 will be at the study site and you will complete:
- Symptom and quality of life questionnaires
- EGG measurement test
- Blood draw for GI hormones.
- TEA or Sham TEA use and testing

This visit could last up to 7 hours.

Week 7, 8 and 9
You will not have a study visit on these weeks. However, you will be asked to wear the TEA or Sham TEA as instructed and complete questionnaires at home.

Week 10 (Visit 4)
Visit 4 will be at the study site and you will complete:
- Symptom and quality of life questionnaires
- EGG measurement test
- Blood draw for GI hormones
- TEA or Sham TEA use and testing.

This visit could last up to 7 hours.

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?
Your participation in this study will include 4-6 study visits over the course of 10 weeks.

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

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?
Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes testing levels of special digestive hormones.

How will your data and/or biospecimens be shared now and in the future?
Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen 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 and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

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

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an Institutional Review Board (IRB), is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you should not participate in this study.

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

Blood Draw
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

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.

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. The information gained from this research study will contribute to the medical community's understanding of gastric motility disorders.

8. What are your options if you do not want to be in the study?
You do not have to join this study. You will continue to follow up with your referring gastroenterologist and receive standard clinical care. 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. 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?
Your information will be stored in a locked, secured cabinet located in the John Hopkins Bayview Rheumatology outpatient clinic. Biospecimen testing will be performed using de-identified samples.

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.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

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, Zsuzsanna H McMahan MD at 410-550-7335. 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 Zsuzsanna H McMahan MD at 410-550-7335 during regular office hours and at 410-550-0100 after hours and on weekends. If this doctor is not available, the operator will page the "on call physician."

17. 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

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).