Research Consent /Authorization Form

IRB # 2020-0465

Study Name: ECG Belt

Full Title: ECG Belt to Assess Electrical Synchronization in Patients with Left bundle branch Area Pacing and His-Purkinje Conduction System Optimized Cardiac Resynchronization Therapy

Study Doctor: Dr. Pugazhendhi Vijayaraman

Site(s):Geisinger Wyoming Valley

Study Phone Number: 570-808-6020

24-Hour Phone Number: 570-808-7300 (Hospital Operator)

Funded by: Medtronic, Inc.

We are asking you to be in a health research study.

You do not have to be in this study. Your access to care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

This study is funded by Medtronic, Inc. Dr. Vijayaraman, the lead study doctor at Geisinger, also receives payment for providing education to other Cardiologists for Medtronic, Inc.

What Should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your routine care.
- Ask questions.
- Take time to think about this, and talk to your family and friends.

Why is this study being done?

We are asking you to join this study because you had a special type of pacemaker implanted to help treat heart failure or a slow heartbeat.

Your pacemaker uses wires (leads) to send electrical signals to your heart. These signals help the left and right sides of your heart pump together. Signals are also sent back to the pacemaker to record how your heart is beating.

This study is being done to learn more about the properties of the electrical signals by using a new system called the Medtronic ECG Belt Research System. An ECG (electrocardiogram) is a graph of the electrical activity of the heart. We want to see how well the Medtronic ECG Belt system lets us understand the properties of the electrical signals.

The study system is not approved by the Food and Drug Administration (FDA) and is considered investigational. Medtronic is seeking to obtain FDA approval for the ECG Belt.

Study Device

The ECG Belt Research System includes a belt called an electrode array. This is called the ECG Belt. The ECG Belt wraps around your chest and back. It has electrodes on each side. The electrodes make contact with your skin and are used to measure the electrical activity in your heart. The data that the electrodes collect are passed through the ECG Amplifier. This helps the study system software process the data.

The study system will be removed once study testing is complete.

Who will be in the study?

About 20 people will join at Geisinger.

How long will I be in the study?

You will be in the research study for about 1 week.

The study doctor could decide to take you off this research study if:

- The doctor believes it is in your best interest
- You do not follow the study direction
- For any other reason

What will I be asked to do?

Baseline Visit

If you agree to join this study, you will be asked to sign and date this form.

You will have tests done to see if you qualify to be in the study. We will do the following:

- Collect general information about you such as age, gender, race, ethnicity
- Review your medical history, including any history of tobacco use
- Review your medications
- Classify your heart failure according to the New York Heart Association (NYHA) scale
- Collect information about your implanted device
- ECG (traces your heart's electrical activity)

If you qualify for the study, you will have the ECG Belt procedure. The ECG Belt will be attached to your chest and readings will be collected at the clinic. This procedure may take about 50 minutes to complete. After the readings are collected, we will remove the ECG Belt from your chest.

Follow-up Phone Call (1 week)

We will call you in about one week to ask about any changes to your health.

If you have any side effects from the ECG Belt System that are ongoing, your doctor may ask you to come in for an extra visit to monitor your health. Otherwise, this will be the last contact for the study.

You will continue to be followed in the device clinic per your routine care.

What about Pregnancy?

The study device may cause risks to an unborn child. For this reason, you cannot join this study if you are pregnant.

If you are a woman who is able to become pregnant, you will have a urine pregnancy test prior to the ECG Belt procedure. This is done as part of your routine care.

What are the costs?

The ECG and the ECG belt procedure at the baseline visit are done for the study only and will be done at no cost to you or your insurance.

All other tests/and procedures listed in this form are considered routine care (the care you would have received if you were not in this study). The tests and procedures ordered as part of your routine care could be different. Any items done as part of your routine care will be billed to you or your insurance.

Will I be paid?

You will not be paid for joining this study.

Can being in this study help me?

This study might or might not help you. We hope that what is learned from this study will help others in the future.

What are the risks?

ECG Belt Research System Risks

Risks of the ECG Belt Research system include, but are not limited to:

- allergenic reaction
- skin redness or irritation
- discomfort from the additional ECG Belt electrodes
- minor pain or discomfort while attaching and detaching multiple electrodes to the skin
- discomfort due to lying on the ECG Belt.

Since a larger surface is covered by the ECG Belt, the area of skin redness or irritation may be larger than with standard ECG electrode systems.

There might be effects that we do not know about yet.

What if I am harmed?

If you are ill or injured due to this study, call your study doctor right away. Call: Dr. Pugazhendi Vijayaraman at 570-808-6020.

Medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay you for discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will view and collect information that is in your medical record. We will collect information about you during this study. Some of this information will be kept in a research record at Geisinger. These records will be kept for at least 6 years and then destroyed. Any

information placed in your medical record will be a permanent part of your medical record.

Your primary care doctor or specialist may receive information about your participation in this study.

We will share your information with Medtronic and its partners.

Staff working for Medtronic could be present during your Baseline visit at Geisinger.

By signing this form, you are giving Geisinger permission to use and share your health information. It can be shared indefinitely for purposes of this study. If you change your mind, tell us in writing to stop using and sharing your information.
Write to:

ECG Belt Study
Dr. Pugazhendhi Vijayaraman
Geisinger Clinic
1000 East Mountain Blvd
Wilkes Barre, PA, 18711

Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.

If you pass away while talking part in this trial, the study staff may get in touch with your emergency contacts for additional information.

How will others use and share my information?

The information shared with Medtronic and its partners will include:

- Study ID number
- General information about you such as age, gender, race, and ethnicity

- Medical history
- Information about the medical care you receive during the study

Your information will be shared with Medtronic in a way that does not identify you. The information sent to Medtronic and its partners may be kept and used without end.

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- The Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS)
- Office for Human Research Protections (OHRP)
- Medtronic and its partners
- Government agencies in other countries

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

How is my information protected?

We will take steps to protect your information. Your study information will also be kept in locked offices and on password protected computers. Some laws that protect your information only apply to hospitals, doctors' offices, and other healthcare providers. When your information is shared outside of Geisinger, some federal privacy laws might not apply.

We will share your information with a court of law or the government, in the unlikely event this is required.

Do I have other choices?

You could choose not to be in this study.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

A description of this clinical trial will be available on 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.

What if I have questions or problems?

Call: Dr. Pugazhendhi Vijayaraman at 570.808.6020, if you:

- Have questions, concerns or complaints about the study
- Feel you have had a study-related injury

Call the Geisinger Institutional Review Board (IRB) at:
844-542-3299 or 570-271-8663 (Danville, PA)

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

Signature

I agree to take part in this research study and allow my health information to be used for this research. My questions have been answered. I will get a signed copy of this form.

_____
Research Participant's Printed Name

_____ _____
Research Participant's Signature Date

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

Person Obtaining Consent Signature	Date