Research Consent /Authorization Form

IRB # 2022-0917

Study Name: EC-LBBAP study

Full Title: Intra-procedural Transthoracic EChocardiogram to facilitate LBBAP (EC-LBBAP study)

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 by contacting the study team listed in the box above.

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

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.

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.

Why is this study being done?

We are asking you to join this study because you will need to have a special type of device (pacemaker or defibrillator) implanted as part of your routine care to help treat heart failure or a slow heartbeat.

Your device will use up to three wires 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 implanted device to record how your heart is beating.

Depending on the type of treatment you receive, you could have two wires placed inside of your heart; one on the right side and one on the left side. A third wire may also be placed on the outside of your heart.

Your doctor has determined to use Conduction System Pacing (CSP) as part of your routine care. This type of pacing includes left bundle branch area pacing (LBBAP). It involves placing a wire along a group of specialized cells in your heart that send electrical signals to the heart muscle. This approach is like recreating the normal electrical system of heart to pace both lower heart chambers.

An issue with this type of pacing is that this procedure can be a little longer than other routine care pacing therapies. The x-ray imaging time used during the procedure may also be longer than other therapies. It can also be challenging for doctors to see where the wire is located during the procedure.

This study is being done to see if a procedure called a transthoracic echocardiogram (heart ultrasound) can:

- help doctors with figuring out the wire location during implantation
- reduce the wire placement procedure time
- reduce the x-ray imaging time during the procedure

We want to also see if using a heart ultrasound during your implant procedure will improve the safety and success of the procedure.

For this study, we will also be comparing heart ultrasounds taken using a non-handheld machine with heart ultrasounds taken using a handheld device. We want to see how well handheld ultrasound devices achieve LBBAP procedure success. Both heart ultrasound methods provide the same information and are used clinically at Geisinger.

The heart ultrasound is not used during CSP procedures at Geisinger as part of routine care. This is being done as part of the study.

Who will be in the study?

About 30 people will join this study at Geisinger. There are two groups in this study:

- Group 1: 20 people will undergo the heart ultrasound using a non-handheld ultrasound machine.
- Group 2: 10 people will undergo the heart ultrasound using a handheld ultrasound device.

Enrollment in Group 1 has been completed. If you agree to join the study, you will be in Group 2.

How long will I be in the study?
You will be in the research study for about 3 months.

The study doctor could decide to take you off this research study without your consent if:

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

What will I be asked to do?

Baseline Visit
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
- ECG (traces your heart's electrical activity)

If you are a woman who is able to get pregnant, you will have a urine pregnancy test as part of your routine care prior to your implant procedure.

You may be asked to sign an authorization form for the release of medical Records. This form allows the study staff to obtain your medical records, if you receive care at a hospital outside of Geisinger during the study.

<u>Implant</u>
If you qualify for the study, you will have a heart ultrasound during your implant procedure. This ultrasound is done as part of research. For the

heart ultrasound, a wand is placed on your chest that uses sound waves to make a picture of your heart and shows how the muscle and valves work.

The use of the heart ultrasound may add about 15 minutes of total procedure time. However, we hope that it may lower the x-ray imaging and wire placement procedure times.

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

Your implant procedure will be done as part of your routine care.

We will collect information about your implanted device and procedure as part of the study.

Follow-up Visits (2 Week and 3 Month Visits)
You will be asked to come to the clinic as part of your routine care 2 weeks and 3 months after your implant procedure.

At these visits, you will have the following:

- Physical Exam
- ECG
- Device Interrogation

We will also review your medications and any changes to your health.

The 3 Month Visit will be your last visit for the study. No more study data will be collected, and no additional study visits will occur. You will continue to receive routine care from your doctor.

Study Visits

The following will take place during the study:

Table 1. Study Procedures

Study Procedure	Baseline Visit	2 Week Visit	3 Month Visit
Physical exam	X	X	X
ECG	X	X	X
Urine pregnancy test *	X		
Heart ultrasound	X (during Implant procedure)		
Heart Failure Classification (NYHA)	X		
Device interrogation		X	X

*If applicable

Study tests and procedures

Physical exam: A physical exam will be done at each visit.

Electrocardiogram (ECG): Sticky patches are placed on your chest to measure your heart's electrical activity.

Urine pregnancy test: We will test your urine to see if you are pregnant if you are able to become pregnant.

Heart Ultrasound: A wand is placed on your chest that uses sound waves to make a picture of your heart and shows how the muscle and valves

work. This test will be done as part of the study during your implant procedure.

Heart Failure Classification: We will ask questions about your heart failure symptoms to see what stage of heart failure you have.

Device interrogation: This is done to check to see if your device implant is working properly. A wand is placed over your chest. Data about your heart beat and the life of your device battery are sent wirelessly. If needed, your doctor will change the settings of the device.

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

Will my data be used for future research?
Your information could be stored and shared for future research. Your data will not be used to identify you.

We will not give you any results from these studies.

We may share your information with academic and medical institutions, other researchers, drug and device companies, biotechnology companies and others.

You will likely not directly benefit from future research with your information. What is learned may help develop new scientific knowledge.

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?
There are risks related to your condition and routine care. This form will not list those risks. We will only list the added risks of being in this study.

You may have rare skin irritation or skin redness due to the ultrasound gel used on the skin during the heart ultrasound.

There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

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

What are the risks for a pregnancy?
This study might involve risks to you or your unborn child if you are pregnant. This could include risks that are unforeseen. 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 your implant procedure. This is done as part of your routine care.

What if I am harmed?
If you are ill or injured due to this study, call your study doctor right away. Call: Dr. Pugazhendhi 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.

What are the costs?

The heart ultrasound during your implant procedure is 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 receive if you are not in this study). The tests and procedures ordered as part of your routine care could be different from those described in this form. The costs of your implant device, the implant procedure, and hospital stay are part of your routine care. 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.

How will my information be used, shared and protected?

The Geisinger study staff will view and collect information about you during this study. The information shared with Medtronic, Inc. and its partners will include:

- Information collected about you during the study.
- Information from your medical record. This may include data from non-Geisinger providers.

Some study information will be placed in your medical record. Information in your medical record can be seen by both Geisinger and non-Geisinger providers that care for you.

Some study 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 information will be shared with Medtronic, Inc. in a way that does not identify you. The information sent to Medtronic, Inc. and its partners may be kept and used without end for the research purposes described in this form.

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, Inc. and its partners
- Government agencies in other countries

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

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 do not have to be in this study. You can still receive the implant and pacing procedure as part of your routine care without joining the study.

You have other choices. You could choose:

- Usual care for your illness or condition
- No treatment
- To be in a different study

Your study doctor will talk to you about your choices.

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.

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.

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.

Signature

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 and for future research as explained in this form. If you change your mind, tell us in writing to stop sharing your information. Write to:

EC-LBBAP Study
Dr. Pugazhendhi Vijayaraman
Geisinger Clinic
1000 East Mountain Blvd
Wilkes Barre, PA, 18711-3610

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 I do not sign this form, I cannot join this study.

I agree to take part in this research study and allow my health information to be used and shared as stated in this form. 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 Printed Name

_____ _____
Person Obtaining Consent Signature Date