Research Consent /Authorization Form

IRB # 2020-0831

Study Name: HOT-CRT Study
Full Title: HIS-Purkinje Conduction System Pacing Optimized Trial of Cardiac Resynchronization Therapy (HOT- CRT)
Study Doctor: Dr. Pugazhendhi Vijayaraman
Site(s): Geisinger Wyoming Valley
Geisinger Community Medical Center
Geisinger Medical Center
Study Phone Number: 570-808-6020
24-Hour Phone Number: 570-271-6211 (Hospital Operator)

Funded by: Geisinger Clinic

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.

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 have heart failure and are scheduled to have a special type of device (pacemaker or defibrillator) implanted as part of your routine care.

Your device will use 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.

Two of the wires are placed inside of your heart; one on the right side and one on the left side. The third wire is placed on the outside of the heart. The specific site is different depending on the type of treatment you receive.

This study is being done to compare two different treatment options. You will be assigned to one of two groups.

- Group 1: Biventricular pacing- The third wire is placed near a group of veins (called the coronary sinus) on the back of the heart. This site is used most often in routine care.

- Group 2: HOT-CRT- The third wire is placed on specialized cells (called the HIS Bundle) that send electrical signals to the heart muscle. These cells are between the left and right side of the heart. This approach is like recreating the normal electrical system of heart. In routine care, this is an alternative option.

Normally your doctor would choose which option to use. In this study, the treatment option will be chosen at random, like the flip of a coin. You have an equal chance (50%) of being in either the group. You will not know which group you are in. Your treating doctors will know in order to provide your routine care.

If your assigned treatment option is not successful, the other option will be considered. With this approach, the success of placing the third wire would be very high.

Both options are considered part of routine care. A study that directly compares these two sites has not been done. This study hopes to do that. This study will compare how well the heart pumps when HOT-CRT is used compared to biventricular pacing.

Who will be in the study?

About 100 people will join at Geisinger.

How long will I be in the study?

You will be in the research study for about 6 months.

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?

Study tests that will be done at each visit are listed in Table 1.

Screening

If you join this study, we will review and collect your medical history. We will ask about changes in your health.

You will have tests done to see if you qualify for the study. The tests are listed in Table 1.

You will be asked to sign an Authorization for 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.

Implant
The implant procedure is done as part of your routine care. If you join this study, the site for your third wire will be decided by chance. During the study, your doctor will not tell you which of the two sites was used.

During the procedure, if the third wire cannot be placed at your assigned site, the doctor will place the wire at the other site.

Follow-up Visits (Week 2, Month 3, Month 6)
We will ask about any changes in your health at every visit.

The Month 6 visit will be the last visit for the study.

Study Visits
You will be asked to complete surveys and do 6 minute walk tests for research purposes.

All other tests and the implant procedure listed in this form are considered part of your routine care.

Table 1.

	Screening	Implant	Week 2	Month 3	Month 6
Physical Exam	X			X	X
ECG	X	X		X	X
Heart Ultrasound	X				X
Device Implant		X			
Pregnancy Test*	X				
Surveys	X				X
6 Minute Walk Test	X				X

	Screening	Implant	Week 2	Month 3	Month 6
Device Interrogation		X	X	X	X
Blood work to check:					
Heart function	X				
General health	X				

* Only for women of childbearing potential

Study Tests

ECG: sticky pads are placed on your chest to check your heart's electrical activity.

Heart Ultrasound: A wand is placed on your chest to view your heart.

Device interrogation: A wand is placed over your chest. Data about your heart beat and the life of your pacemaker battery are sent wirelessly.

Surveys: You will be asked to fill out a survey about heart failure and your quality of life.

6 Minute Walk Test: This test is to check how far you can walk during a 6 minute period. We will ask you how you feel after the walk.

Pregnancy Test: If you are a woman who can become pregnant, you will have a urine or blood pregnancy test at the Screening visit.

Blood Tests: We will collect blood samples to check your heart function and your general health at the Screening visit.

What about Pregnancy?

The implant procedure may cause risks to an unborn child. For this reason, you cannot join this study if you are:

- pregnant,
- nursing a child or
- planning to become pregnant during the study.

To join this study, you must have a negative pregnancy test.

During the study, if you think you may be pregnant, tell the study team right away.

What are the costs?

The items below are done for the study only and will be done at no cost to you or your insurance.

- Surveys
- Six Minute Walk Test

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 being part of 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?

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

The implant procedure is part of your routine care. You doctor will talk to you about the risks and you will be asked sign a separate form for the procedure. We do not know of any difference in risk between the two study groups. However, there might be effects that we do not know about yet.

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.

What if I am harmed?

If you are ill or injured due to this study, call your study doctor right away. Call: Dr. 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.

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:

HOT-CRT Study
Dr. Vijayaraman, MD
Wyoming Valley Medical Center
1000 East Mountain Boulevard
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 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?

Information will not be shared outside of Geisinger in a way that will identify you directly.

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)

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.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world, will not identify you directly.

How is my information protected?

We will take steps to protect your information. Data will be stored in a locked office 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 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.

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. 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