SPECTRUM HEALTH

Patient name

DOB

MRN

Physician

FIN

Permission to Take Part in a Human Research Study & HIPAA Authorization for Release of Health Information for Research Purposes

Title of Research Study: Prophylactic Limited Left Sided Maze to Prevent Post-Operative Atrial Fibrillation in Adult Cardiac Surgery Patients PREVENT AF (Feasibility Study)

Sponsor: Charles Willekes, MD

Investigator: Charles Willekes, MD

"You" refers to the subject.

"We" refers to Spectrum Health

We invite you to take part in this research study because you will be undergoing open heart surgery. A common occurrence after open heart surgery is that your heart may temporarily go into an irregular rhythm called atrial fibrillation. This happens to about 30-60% of patients undergoing open heart surgery. If it happens, it usually occurs 2 to 3 days after surgery and often resolves before you go home.

Atrial fibrillation is an abnormal and irregular heart rhythm in which electrical signals are generated chaotically throughout the upper chambers of the heart. Being in this rhythm may cause a risk of blood clots forming in your heart and causing a stroke. Atrial fibrillation could make your hospital stay longer. And, even after your heart returns to its normal rhythm, your doctor may want you to take blood thinners and other medications.

Some patients having open heart surgery also have a history of atrial fibrillation. If that is the case, it is common to have an additional procedure called a surgical maze at the same time as your open heart surgery. A surgical maze procedure has two parts. The first part of the surgical maze procedure is called a pulmonary vein isolation ablation. This is where energy is applied to a specific area on the outside of your heart to create scar tissue. The created scar tissue may prevent the heart from going into atrial fibrillation. Second, it involves removing an area of the heart called the left atrial appendage. This is a part of the heart where blood clots can form and lead to strokes.

What you should know about a research study?

- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you talk to the investigator, Dr Charles Willekes at 616-459-7258 or members of the research team at 616-391-3886.

This research has been reviewed and approved by the Spectrum Health Institutional Review Board. You may talk to them at (616) 486-2031 or irb@spectrumhealth.org for any of the following:

- Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or research team.
- You want to talk to someone besides the investigator or research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why are we doing this research?

Currently there is no treatment to prevent the atrial fibrillation that happens as an occurrence after open heart surgery. We are doing this research to show that performing a surgical maze procedure (left atrial appendage amputation and pulmonary vein isolation ablation) along with open heart surgery, not just in patients who have a history of atrial fibrillation, may decrease and/or prevent the occurrence of atrial fibrillation in postoperative open heart surgery patients.

This research study involves the use of the AtriCure® Synergy Ablation System. This is an FDA approved device used to perform the pulmonary vein isolation ablation procedure in patients having open heart surgery who also have a history of atrial fibrillation. The device has been used since 2010 and has shown to be 74% effective here at Spectrum Health in treating and preventing atrial fibrillation a year after heart surgery for those patients that had a history of atrial fibrillation before surgery.

The device is not approved for the prevention of atrial fibrillation. Therefore, having a surgical maze (pulmonary vein isolation ablation and left atrial appendage amputation) along with your open heart surgery is considered experimental.

How long will I be in the research?

We expect that you will be in this research study for approximately one year. Your study participation will begin the day you sign the research study informed consent and ends 365 days after you had surgery.

How many people will be studied?

This research study is only being conducted at Spectrum Health.
We expect to enroll up to 60 people in this research study.

What happens if I say yes, I want to be in this research?

Your heart surgeon will explain the study to you in detail and give you a consent form. You will have enough time to read it, review it, share it with your family and friends, and to ask questions.

If you agree to take part in the study you will sign the consent and a copy will be given to you. Your personal information will be put into a computerized database called REDCap for randomization. You will be assigned to one of two groups. One group of patients, called the control group, will receive their scheduled open heart surgery and the other group of patients, called the treatment group, will receive their scheduled open heart surgery plus the surgical maze procedure (left atrial appendage removal and pulmonary vein isolation ablation). The group you are assigned to will be chosen by chance like flipping a coin. This is called randomization. Neither you nor the study doctor will choose what treatment you get. You will have a fifty-fifty chance of being assigned to either treatment. You will be told which treatment you were assigned to.

On the day of your scheduled open heart surgery you will be brought to the operating room and given a general anesthetic. You will be asleep during surgery. Next your heart surgeon will place you on the heart lung bypass machine and will perform the surgical maze procedure (left atrial appendage amputation and pulmonary vein isolation ablation) if you were randomized to the treatment group.

The surgical maze procedure has 2 parts. The first part of the surgical maze procedure is called a pulmonary vein isolation ablation. This is when radiofrequency energy is applied very briefly to a specific area on the outside of your heart. This application of energy creates a small amount of scar tissue on an area of the heart that atrial fibrillation is known to come from. This area is where the four pulmonary veins connect to the left atrium. Creating this specific scar tissue may prevent atrial fibrillation from occurring.

The second part, left atrial appendage amputation, involves removing a small piece of your heart called the left atrial appendage. It is unclear what purpose, if any, this piece of your heart serves, and is also an area where blood clots can form and lead to strokes.

Performing the 2 parts of the surgical maze procedure (left atrial appendage amputation and pulmonary vein isolation ablation) takes a short amount of time. Then your heart surgeon will complete the rest of your scheduled open heart surgery according to standard of care.

If you were randomized to the control arm of the study, you will have your open heart surgery without the surgical maze procedure.

Patients in the treatment arm of the study (left atrial appendage amputation and pulmonary vein isolation along with open heart surgery) will have a transthoracic echocardiogram done before going home from the hospital. This is a test where an ultrasound probe and warm lubricant are placed on the outside of your chest to see how your heart is functioning. This test may cause a little bit of temporary discomfort. The rest of your postoperative care will follow the current standards of care in place for all open heart surgery patients.

We will follow you during your hospitalization and will be at your postoperative visit with your heart surgeon. We will continue to follow you by a review of your electronic medical record (EMR) until 365 days after your procedure. If we are unable to find information about you and your health in the EMR, we may contact you by phone.

Your health information will be collected and entered into a database.

What happens if I say no, I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. A refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

Instead of being in this study, you may choose to have open heart surgery and not participate in research. You will receive the usual standard of care that all open heart surgery patients receive. This includes a medication called a beta blocker which is given to all patients prior to having heart surgery. Your heart surgeon will discuss the risks and benefits of your procedure with you.

What happens if I say yes, but I change my mind later?

You can agree to take part in the research now and stop at any time it will not be held against you. If you decide to leave the research, contact the investigator.

Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data and entered into the study database to evaluate outcomes.

What are the possible risks and discomforts I may have if I take part in this study?

The risks with this study are similar as for any patient having open heart surgery and are listed below.

If you are randomized to the treatment group having the surgical maze procedure (left atrial appendage amputation and pulmonary vein isolation ablation) in addition to your open heart

surgery, there may be a slight increased risk of bleeding and slightly longer time on the heart lung bypass machine. Your surgeon will discuss those risks with you. Other possible risks are listed below:

- Death
- Excessive bleeding that may require re-intervention or another surgery
- Cardiac tamponade (a collection of blood around the heart)
- Pulmonary vein stenosis or narrowing of the veins that brings blood from the lungs to the heart
- Restrictive or constrictive pericarditis (inflammation of the sac surrounding the heart)
- Infection that may result in sepsis (infection in the blood) or endocarditis (an infection of the heart)
- Myocardial infarction or heart attack (decreased blood flow to the hear resulting in heart muscle death)
- Stroke or transient ischemic attack (TIA)
- Thromboembolism (blockage of a blood vessel by a blood clot that has become dislodged from another site)
- Diaphragmatic (phrenic nerve) paralysis
- Esophageal-left atrial fistula or esophageal rupture (a hole in the esophagus or a hole between the heart and esophagus)
- Atrial or ventricular perforation (a hole in the wall of the heart)
- Atrial or ventricular rupture (a hole or tear in the heart muscle)
- Atelectasis or underinflated lungs
- Pneumonia or a lung infection
- Congestive heart failure or failure of the heart to supply the body with enough blood
- Cardiac valve injury
- Persistent pneumothorax or collapsed lung
- Excessive pain and discomfort
- Deep sternal wound infection (mediastinitis)
- Perioperative atrial or ventricular rhythm/conduction disturbance (abnormally fast, slow, or irregular heart rhythm)
- Pericardial effusion (a collection of fluid around the heart)
- Injury to the great vessels
- Injury to unintended surrounding tissues, including tears and punctures
- Extension of cardiopulmonary bypass time on the heart/lung machine

Potential risks already listed above that may be associated with the surgical maze procedure (left atrial appendage amputation and pulmonary vein isolation ablation) include:

- additional time on Cardiopulmonary Bypass Pump
- additional time on the breathing machine during surgery, and additional anesthesia
- Pulmonary vein stenosis or narrowing
- Need for a permanent pacemaker
- Bleeding
- Unintentional damage to tissue near the pulmonary vein
- Atrial flutter

Under Michigan law, an HIV and hepatitis test may be done on you without your consent if a healthcare worker is exposed to your blood or other bodily fluids. If the results of an HIV or hepatitis test indicate that you are HIV or hepatitis positive, you will be told about these results and given information about the disease, treatment resources, and other options.

In addition to these risks, this research may hurt you in ways that are unknown. If we learn of new risks that we think might affect your desire to stay in the research we will tell you. It is possible, if major risks are discovered after the study is finished, we may attempt to contact you.

Will I need to pay for any of the tests or procedures in the study?

You or your health insurance will be billed for your open heart surgery. If your insurance company requires any co-payment or deductible, you will be responsible for making that payment. If you are randomized to the treatment group, neither you or your insurance company will be billed for the surgical maze procedure (left atrial appendage removal and pulmonary vein isolation ablation) which is done along with your open heart surgery. Neither you nor your insurance company will be billed for the pre-discharge transthoracic echocardiogram required for patients in the treatment arm of the study (left atrial appendage removal and pulmonary vein isolation along with open heart surgery).

You will not receive any monetary compensation for being in this research study.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include not having your heart go into atrial fibrillation after your heart surgery. Another possible benefit may be a shorter hospital stay and no need to be on antiarrhythmic or anticoagulation medications.

Your risk of developing atrial fibrillation after heart surgery is about 30%. Since the procedure will be performed to prevent atrial fibrillation, there is around a 70% chance that you may not benefit from the surgical maze (left atrial appendage amputation and pulmonary vein isolation ablation) procedure.

How will the information identifying me be kept confidential?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

- The Investigator and his research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and staff
- Food and Drug Administration (FDA)
- Agencies that accredit the hospital or research program

Some of these organizations may be given direct access to your medical records for verification of the research procedures/data involved. By signing this document, you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your personal information. These are described in a later section.

Can I be removed from the research without my OK?

While not expected, the doctor in charge of the research study can remove you from the research study without your approval if it is felt to be in your best interest.

What if I'm injured or made sick from the research?

As a research participant, there is the possibility you may be harmed as a result of being in this study. It is the nature of medical research that not all adverse events (unfavorable side effects) are preventable or can be predicted. If you are injured as a result of taking part in this research study and need medical care, please tell your study doctor right away. Medical care will be made available to you just as it is to the general community.

However, Spectrum Health has no funds set aside for financial compensation for research-related injury and any associated cost of medically treating the injury. Therefore, medical care for a research-related injury will be billed to either you and/or your insurance. Your insurance may not be willing to cover the entire cost for treating a research-related injury, but you will not be responsible for that cost. If you have no insurance, you may be responsible for all costs associated with medical care for a research-related injury.

Contact Charles Willekes, MD at 616-459-7258 for more information. By signing this consent form you will not be waiving any of your legal rights which you otherwise would have if you were not participating in a research study.

What else do I need to know?

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.

HIPAA Authorization for Release of Health Information for Research Purposes

The information we are asking to use and share is called Protected Health Information (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

What will be done with my information?

Your health information will be collected and entered in a database along with the information from other people taking part in this study.

Why am I being asked to release it?
Your health information will be used by Charles Willekes, MD and the research team to conduct the study and evaluate outcomes.

What will be released?
To complete this research study, we will need to collect and release (disclose) information about you. This information may include:

- Your date of birth, name, contact information, and medical record number.
- Existing medical records and medical history.
- New health information collected for purposes of this study.

Who will use it or share it?
- The investigator and his research staff
- Spectrum Health staff or its agents
- The Spectrum Health Institutional Review Board (IRB) and its staff
- The Food and Drug Administration (FDA)
- Agencies that accredit the hospital or research program

Once your protected health information has been disclosed it is possible that anyone who receives that information may re-disclose it. Because some of these individuals who receive your protected health information may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Spectrum Health. Therefore, we share your information only if necessary and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

How long will my health information be used?
This authorization has no expiration date.

Can I stop my protected health information from being collected?
You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask. If you want us to stop, you must tell us in writing:

Charles Willekes, MD
c/o Cardiovascular Research
330 Barclay, Suite GL1/ MC 289
Grand Rapids, MI 49503

What happens if I do not want you to collect and release my information?
If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.

When will it be destroyed?

We do not know when your information will no longer be used. Therefore, the information will be kept for an indefinite length of time.

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	