IMPROVING MITRAL REPAIR FOR FUNCTIONAL MITRAL REGURGITATION (IMPROVE-FMR)

NCT03366649

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You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 140 people who are being studied at Emory.

Why Is This Study Being Done?
This study is being done to answer the question: *How well does the mitral valve and heart function after mitral valve surgery?*

You are being asked to be in this research study because your cardiologist has determined that you have functional mitral regurgitation due to cardiomyopathy and you need to have it corrected.

Do You Have To Be In the Study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What Do I Have To Do If I Choose to Participate in This Study?
If you are eligible and want to be part of the study, we may enroll you prior to heart surgery (Registry 1). You will participate for 12 months from your surgery date. If you are enrolled after your heart surgery, you will enter the study at 6 months from your surgery date (Registry 2). The researchers will ask you to do the following: respond to questions about your health and quality of life, ask you to complete a walking test, obtain blood, and image your heart with ultrasound and/or MRI. The procedures that are not part of your standard care and performed for study purposes will be paid for by the study.

How Is This Study Going to Help You?
If you are in the study, you will be helping the researchers answer the study question.

What Are the Risks or Discomforts I Should Know About Before Making a Decision?
The study will take time. This study is not testing a new device or drug. It is only examining how well your mitral valve is performing after your surgery, and how well your heart is responding. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include feeling some discomfort when drawing blood and when undergoing cardiac imaging procedures, claustrophobia if undergoing magnetic resonance imaging,, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
If you decide not to be in this study, there is care available to you outside of this research. You will receive established standard treatment for correcting mitral regurgitation whether you take part in the study or not. This usually includes mitral valve repair or mitral valve replacement.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject and HIPAA Authorization

Title: **IMPROVE-FMR: Improving Mitral Repair for Functional Mitral Regurgitation**

Principal Investigator: [redacted]**, PhD**

Surgical Co-Investigators: [redacted]**, MD,** [redacted]**, MD**

Sponsor: National Heart, Lung and Blood Institute (NHLBI)

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you.
- Please listen to the study doctor or study staff explain the study to you.
- Please ask questions about anything that is not clear.

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

If the patient is unable to read, an impartial witness should be present during the entire informed consent discussion.

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 may search this Web site at any time. A description of this clinical trial may also be available on other similar sites in order to fulfill legal and regulatory requirements in your country.

What Is the Purpose of the Study?

Your cardiologist has determined that you have functional mitral regurgitation due to cardiomyopathy and you need to have it corrected. Mitral regurgitation is when the valve leaks blood backwards in the heart. You are either scheduled for surgery or you have already undergone surgery and are within 6 months after the surgery. Prior to surgery, tests are done so that the cardiologist and surgeon understand why and how much your mitral valve is leaking. The surgeon will review these tests to determine the best way to correct your mitral valve.

This study is looking at two of the different ways your valve can be corrected. One way is to use a ring to help restore a part of your mitral valve to its natural shape, thus reducing or eliminating blood leaking through the valve. The second way uses the ring and also tightens the muscles that connect the valve to the heart muscle, which helps

restore the entire valve to its natural shape. Currently, it is not known which is the best way to fix the leaking mitral valve. The study team wants to know if the pre-operative studies correlate with how your mitral valve works after the surgery and which surgery has a better outcome. Your cardiologist or surgeon will describe the surgery to you in more detail. If you have questions about the surgery, please ask one of them.

We plan to enroll 140 people in this study, 125 who only have the ring placed during the surgery and 15 who have both the ring placed and the muscles tightened. The length of time you will be in the study is 12 months.

What Will I Be Asked To Do?

If you agree to be in this study, you will need to sign this consent so that the study team can collect information from the tests you had before and after the surgery. The study team will also collect information if you have been re-admitted to the hospital.

Pre or During Surgery

Blood will be drawn and stored for later use in this study. All other tests that your doctor requires are necessary regardless of your participation in this study.

At Discharge and 1 Month After Surgery

Blood will be drawn and a transthoracic echo will be performed at discharge and 1 month after surgery to see how your heart is working. All other tests that your doctor has recommended are necessary regardless of your participation in this study.

You will come back for two additional visits after the surgery at 6 months and 12 months.

6-Month Visit

At this visit, the following will occur:

- Complete quality of life questionnaires – these surveys ask questions about how you are feeling, your activity level, pain, emotions and general health questions. These should take no more than 15 minutes to complete.

- You will have a transthoracic echo (ultrasound of the heart) to see how your mitral valve is working.

- *6 minute walk test*
  You will be asked to walk for 6 minutes to see how far you can walk. Your heart rate, blood pressure and oxygenation level will be measured before and after the test. If you cannot walk for the full 6 minutes and need to stop, the reason why you stopped will be recorded.

- Your blood will be drawn to check to see how your heart is working.

12-Month Visit

At this visit, the following will occur:

- Complete quality of life questionnaires – these surveys ask questions about how you are feeling, your activity level, pain, emotions and general health questions. These should take no more than 15 minutes to complete.

- You will have a transthoracic ultrasound of your heart to see how your mitral valve is working.

- *6 minute walk test*

You will be asked to walk for 6 minutes to see how far you can walk. Your heart rate, blood pressure and oxygenation level will be measured before and after the test. If you cannot walk for the full 6 minutes and need to stop, the reason why you stopped will be recorded.

- Your blood will be drawn to check your heart health.

- You will also be asked to have an MRI of your heart or a transesophageal ultrasound of your heart (a probe is placed in your throat into your 'food pipe' to look at your heart from that point of view).

What Are the Possible Risks and Discomforts?

Participation in the study may involve some risks, as outlined below.

Loss of Confidentiality

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. This risk is small because we have put in place a number of protections to prevent this from occurring.

Reproductive Risks

If you are a woman: to protect against possible side effects from the heart surgery and anesthesia, women who are currently pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. A pregnancy test will also be given before you begin the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately.

Blood Draw Risks

Blood collection will require insertion of a needle into one of your blood vessels. You may experience some pain and bruising at this site. You may feel faint. There is also a risk of infection.

The blood samples acquired from you will be stored for measuring the levels of some proteins that may be indicative of your heart health. Your sample will be coded and will not have any information that will link it to your medical record, to anyone other than this study investigators. This information is only for research purposes and thus will not be used in making any medical decisions that impact your treatment. No genetic tests will be performed on these samples, and your consent will be sought if any future studies are planned.

Six Minute Walk Test Risks

While you are walking, you may feel chest pain, increase in your heart rate, light-headedness or confusion, tiredness, short of breath, leg cramps or not being able to walk. If you have any of these or another reason of not feeling well, please tell the study team immediately.

Radiation Risks

You will be exposed to radiation from fluoroscopy. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal. You will receive radiation exposure from the fluoroscope that produces pictures of your internal organs. Your soft tissue and bones will receive a radiation exposure, but the highest radiation exposure will be to your skin. Very high

skin exposure can cause reddening of the skin, blistering and even ulceration. Sometimes this will be delayed for weeks or months after exposure. If you should experience skin discomfort in the area that was pictured, report this to your personal physician.

MRI Risks

MRI exams use powerful magnets to create images of the body. You may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

Contrast Agent Risks

Your fluoroscopy and MRI procedures may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

Incidental Findings

Ultrasounds of the heart and MRIs that are done for research purposes only will not be read by a health professional. Those that are part of your standard clinical care will be read by a health professional as part of your care. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

New Information

The researchers may learn something new during the study about the risks of being in it. If this happens, they will tell you about it in a timely manner. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I Benefit Directly From the Study?

This study is not designed to benefit you directly. Your mitral regurgitation may be fully corrected using either of the two techniques, or one technique may be significantly better than the other. However, there is no way to predict the outcomes at this stage and the data and knowledge we obtain from this study will inform future decisions.

Will I Be Compensated For My Time and Effort?

You will be compensated for the 6 month and 12 month visits, at $150 per visit. These are the only two visits that are non-standard of care visits, and thus we will compensate you for your time and effort. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

In Case of Injury

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you get medical treatment. Emory and Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused

by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.
If you believe you have become ill or injured from this research, you should contact Dr. [redacted] at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs
The study sponsor will pay for certain items and services that you may receive if you take part in this study. Those costs covered by the sponsor will only be relevant to the research items of this study.

You will have to pay for the items or services for which the study sponsor does not pay, i.e. those which are part of your routine care. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Saint Joseph's Hospital and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

What Are My Other Options?
If you decide not to be in this study, there is care available to you outside of this research. You will receive established standard treatment for correcting mitral regurgitation whether you take part in the study or not. This usually includes mitral valve repair or mitral valve replacement. The study doctor will discuss these with you. You do not have to be in this study to be treated for your mitral valve regurgitation.

Taking part in this study, however, may make you unable to take part in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like www.Clinicaltrials.gov and www.ResearchMatch.org.

How Will You Protect My Private Information That You Collect in This Study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Medical Record

If you are or have been an Emory and Saint Joseph's Hospital patient, you already have an Emory and Saint Joseph's Hospital medical record. If you are not and have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will be put in your Emory and Saint Joseph's Hospital medical record. Emory and Saint Joseph's Hospital may create study information about you that can help with your care, for example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. Laws like the HIPAA privacy rule will protect the confidentiality of the study information in your medical record. State and federal laws may not protect the research information from disclosure.

Emory and Saint Joseph's Hospital do not control results from tests and procedures done at other places, so these results will not be placed in your Emory and Saint Joseph's Hospital medical record. They will likely not be available to Emory and Saint Joseph's Hospital to help take care of you. Emory and Saint Joseph's Hospital do not have control over any other medical records that you may have with other healthcare providers. Emory and Saint Joseph's Hospital will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let your health providers know.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI That Will be Used/Disclosed

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Lab test results.

Purposes for Which Your PHI Will be Used/Disclosed

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Authorization to Use PHI is Required to Participate

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Heart, Lung and Blood Institute (NHLBI) is the sponsor of the study. The Sponsor and its authorized representatives may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor and its authorized representatives may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including the Office for Human Research Protections (OHRP).
    - Public health agencies.
    - Research monitors and reviewers.

- Accreditation agencies.
- Authorized representatives of the National Heart, Lung, and Blood Institute, the sponsor of this research.

Expiration of Your Authorization
This authorization will begin upon signing this document and does not have an expiration date.

Revoking Your Authorization
If you sign this form, at any time you may revoke (take back) your permission to use your information. If you want to do this, you must write to:

[redacted], PhD
Assistant Professor of Cardiothoracic Surgery
Program Faculty in Biomedical Engineering
[redacted]

At that point, the researchers would not collect any more of your PHI. They may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization, you will not be able to stay in the study. Additionally, the researchers and the sponsors may continue to use and disclose the information they have already collected as permitted by the informed consent form.

Other Items You Should Know About Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information will not be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the law. The Sponsor and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI until the study is complete. When the study ends, and at your request, you generally will have access to your PHI in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations and/or for other purposes besides this study.

You may exercise your right to access and correct your information by contacting your physician.

A court of law, could order that medical records be shown to other people, but that is unlikely. Therefore, absolute confidentiality cannot be guaranteed.

Contact Information

Contact Dr. [redacted] at [redacted]:

- if you have any questions about this study or your part in it;
- if you feel you have had a research-related injury, or;
- if you have questions, concerns or complaints about the research.

Contact the Emory Institutional Review Board at [redacted] or [redacted]:

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Saint Joseph's Hospital of Atlanta and have a question about your rights, please contact [redacted] at the Emory Saint Joseph's Research Institute via phone at [redacted]

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**