WIRE-IT (Wire Instrumentation using Radiofrequency Energy to Impact Transseptal Efficiency)

Consent Form Approval Date: 10/14/21
NCT04645342

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: WIRE-IT (Wire Instrumentation using Radiofrequency Energy to Impact Transseptal Efficiency)

This is a medical research study. Your study doctor(s), Gregory Marcus, MD or Thomas Dewland, MD, or one of their associates from the Division of Cardiology at UCSF, will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you are scheduled to have a left atrial ablation procedure for your atrial fibrillation or atrial flutter.

Why is this study being done?

The purpose of this study is to evaluate the effectiveness and safety of a new technique for transseptal puncture. Transseptal puncture is an important part of your upcoming atrial fibrillation or atrial flutter procedure. The transseptal puncture allows your doctor to place catheters in the left atrium of the heart, which is necessary for the treatment of your arrhythmia.

Transseptal puncture involves crossing the wall between the right and left atrium of the heart with the ablation catheter and sheath. This is performed from your leg under x-ray guidance. Traditionally, transseptal puncture has been performed by pushing a needle across this thin membrane (called the fossa ovalis). Electrical (radiofrequency) energy is applied to the needle to help it pass across the membrane. Recently, a new technique has been developed that uses a radiofrequency wire to cross the fossa ovalis. Both the needle and wire methods have been approved by the FDA, but we do not know if one is better than the other. This study seeks to compare the needle and wire methods of transseptal puncture to see if one method is faster or safer than the other.

As above, transseptal puncture is an essential part of your upcoming procedure. If you choose to participate in the study, you will be randomized to one of the two techniques. If you do not participate in the study, your doctor will choose one of the two methods to use during your procedure. Your doctor is familiar with both methods and tools.

Funding Organization: Baylis Medical is funding this study.

How many people will take part in this study?

About 72 people will take part in this study.

What will happen if I take part in this research study?

If you choose to take part in this study and are eligible, you will still have the medical procedure (called catheter ablation), which you are already planning to have, to help treat your abnormal heart rhythm. You will be put into one of two study groups by chance and will have the wire access system (Device System 1) or the needle (Device System 2) used in your ablation procedure. You will be in this study for about 12 months in total and will need to visit the clinical site only once, the day of your ablation procedure (which you are already coming in for). The follow-up visits 3 months post-ablation, 6 months post-ablation, and 12 months post-ablation can either be done when you come in for routine clinical care or remotely over the phone.

Before you begin the main part of the study...

You will need to have the following "screening" exams to find out if you can be in the main part of the study.

- **Medical chart review:** Your medical chart will be reviewed by the study doctors to look at your medical history.
- We will ask you a series of questions to ensure you are eligible for the study.

It is expected that completion of the screening exams will take around 10 minutes.

During the main part of the study...

If the screening exams show that you can continue to be in the study, and if you choose to take part, then you will have the following tests and procedures done.

Initial Remote Visit: Consent and Enrollment
During this first visit (which may be done at the same time as your screening visit) you will be asked study questions, including those regarding your health history and demographics. You will be randomized into one of the two study groups described below.

- If you are in group 1, you will receive the ablation procedure to treat your abnormal heart rhythm and we will use Device System 1, the wire access system, during the transseptal part of the procedure (the part of the procedure that allows access to the left atrium, where the ablation will then be performed).
- If you are in group 2, you will receive the same ablation procedure that group 1 will receive to treat your abnormal heart rhythm, but we will use Device System 2, the needle, during the transseptal part of the procedure (the part of the procedure that allows access to the left atrium, where the ablation will then be performed).

This visit will take 15-20 minutes.

Day of Your Ablation:
No matter what group you are in, the procedure should take 4-6 hours in total, including the time needed to prepare for the procedure. This time is expected to be the same whether you participate in the study or not.

Second Remote Visit (3 Months after Study Ablation):

The study team will check in with you and ask some questions about your health over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF. This visit will take 10-15 minutes.

Third Remote Visit (6 Months after Study Ablation):
The study team will once again check in with you and ask some questions about your health over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF. This visit will take 10-15 minutes.

Fourth Remote Visit (12 Months after Study Ablation):
During this final visit, the study team will check in with you and ask some questions about your health over the phone or if they meet with you during a visit to see your doctor. You also have the option to answer these questions in-person at UCSF. This visit will take 10-15 minutes.

You will be provided with telephone and email contact information for both the study doctors and study coordinators.

How long will I be in the study?

After the study procedure to treat your heart rhythm, you will be in the study for the next 12 months. The three follow-up visits will take place at 3 Months after your ablation, 6 Months after your ablation, and 12 Months after your ablation. The three follow-up visits can all be done remotely or during a regularly scheduled doctor's visit.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctors if you are thinking about stopping or decide to stop.

The study doctors may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

The ablation procedure used in this study involves several risks. Because you are already scheduled to undergo this procedure with your doctor, you will be exposed to these potential risks whether you have the ablation procedure as part of this study or you have the procedure and are not in the study.

Known and potential risks and discomforts of the ablation procedure: Complications occur in less than 5% of people who have an ablation procedure.

- Bleeding at the site where the catheter (thin tube) is inserted into your leg. This will usually stop on its own, but in rare cases (<1%) you may require a blood transfusion or a surgical procedure to fix the bleeding.

Very rare (1% or less) potential risks of the ablation procedure:

- Stroke, heart attack, or death
- Serious damage to your kidney(s) from dye used to help see your blood vessels during the procedure

- Puncture of the heart muscle that requires either drainage through the skin or emergent heart surgery
- Damage to the heart valves or the heart's electrical system which may require additional treatment such as heart surgery or insertion of a permanent pacemaker
- Blood clots in your legs or lungs that could lead to difficulty breathing and may require a blood thinning medication
- Injury to organs/structures that are close to the heart, including the esophagus, lungs, or nerves

Unknown risks:

- The methods of the ablation procedure may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.
- There may be differences in risks between the two transseptal approaches (wire versus needle). However, based on the current scientific evidence, it is not known whether the risks noted above are different with these different transseptal techniques. The purpose of this study is to help determine if there is any difference between the two approaches.

Radiation risks:

- No radiation risk beyond routine clinical care: This study involves radiation exposure as part of routine clinical care. You will not receive additional radiation as a result of participating in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

In every procedure, all precautions will be taken to avoid potential complications. For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

You will have the same potential benefits of the ablation procedure to treat your abnormal heart rhythm, whether (1) you have the procedure as part of this study or (2) if you have the procedure and are not in the study (because you are already scheduled to do this procedure with your doctor). The benefits sought are to help inform future practice and therefore future patients undergoing the same kind of ablation procedure you are currently planned for.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your heart rhythm without being in a study.
- Taking part in another study.
- Getting no treatment.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy.
Some information from your medical records will be collected and used for this study. If you do

not have a UCSF medical record, one will be created for you. Your signed consent form will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of the University of California
- Representatives of the Food and Drug Administration (FDA)

What are the costs of taking part in this study?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Gregory Marcus, MD or Thomas Dewland, MD, if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call them at (415) 353-2554.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at (415) 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Your study doctors, Gregory Marcus, MD or Thomas Dewland, MD, can bereached at (415) 353-2554. The study coordinators are Gracie Wall (415) 562-5906, Kathleen Chang (415) 547-0356, and Michelle Yang (415) 580-1768.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Institutional Review Board at (415) 476-1814.

CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Participant	Signature of Participant	Date and Time
Person Obtaining Consent	Signature	Date and Time