Do you have atrial fibrillation?
Learn about a new treatment study.
About the aMAZE Trial

If you have persistent Afib (atrial fibrillation), you may benefit from participating in a medical research study for patients diagnosed with persistent or longstanding persistent Afib.

The aim of this study is to determine if the combination of two non-surgical treatments—pulmonary vein isolation (PVI) and closure of the left atrial appendage utilizing the LARIAT® procedure—may treat atrial fibrillation more effectively than PVI alone.

The study is called the aMAZE Trial: Left Atrial Appendage Ligation with the LARIAT Suture Delivery System as Adjunctive Therapy to Pulmonary Vein Isolation (PVI) for Persistent or Longstanding Persistent Atrial Fibrillation.

Carefully read this brochure. It will answer many questions you may have about these procedures. Ask your doctor for an informed consent form (“Agreement to be in a Research Study”) and read it, too. If you have further questions, ask your doctor.
What is Afib and why is it a concern?

Afib is an irregular heartbeat, a rapid heartbeat or a quivering of the upper chambers of the heart. It results from a malfunction in the heart’s electrical system.

Afib is the most common heart rhythm disorder in the United States, affecting more than three million people. It can lead to heart and valve diseases, sleep apnea and chronic fatigue. Afib can also lead to two potentially life-threatening conditions: stroke and congestive heart failure.

What is the left atrial appendage (LAA)?

The LAA is a small sac about the size of your thumb that hangs off the left atrium of the heart. Like your appendix, your LAA serves no particular function—but it is a source of electrical activity and may contribute to the abnormal heart rhythm of Afib.

Are there different types of Afib?

Yes. There are several categories of Afib:

• Paroxysmal, or intermittent – episodes of Afib that come and go over the course of seven days or fewer
• Persistent – continuous Afib lasting more than seven days
• Longstanding persistent – continuous Afib that lasts for one year or longer
• Permanent – continuous Afib where a decision has been made not to pursue restoration of sinus rhythm by any means
• Non-valvular – Afib unrelated to valvular disease or prosthetic heart valves

Afib is progressive. So, you may start out with intermittent atrial fibrillation and later develop persistent atrial fibrillation. Or you may experience persistent Afib that later becomes longstanding persistent Afib.
Is Afib curable?

Although medications and treatments—such as those described below—may help relieve symptoms, they do not cure Afib.

What treatments are available for Afib?

The goals of treating Afib are: to restore your heart rhythm to normal; to maintain a normal heart rhythm and prevent recurrence of the irregular rhythm; to protect against blood clots that lead to stroke. Three options are typically considered in the treatment of Afib:

Drugs

Antiarrhythmic drugs can help control irregular heart rhythm, and anticoagulant drugs can help patients with Afib avoid blood clots and stroke. For some patients, drugs alone are a sufficient treatment.

Non-surgical procedures

Electrical cardioversion is a process in which the patient receives an electrical shock on the outside of the chest to “reset” the irregular heart rhythm back to normal.

Catheter ablation involves inserting a catheter (a narrow plastic tube) into a small incision at the patient’s thigh, neck or arm and gently guiding it to the heart. The catheter delivers radio waves, light waves or intense cold to create scar tissue that helps stop erratic electrical signals originating in the pulmonary veins from traveling elsewhere in the heart. A catheter ablation technique called Pulmonary Vein Isolation (PVI) will be used in the aMAZE study.

These non-surgical procedures do not remove or close off the left atrial appendage (LAA) that may be contributing to the irregular heart rhythm of Afib.

Surgery

The third option is a kind of surgery called a maze procedure. There are several variations of the maze procedure; all involve the surgeon closing or removing the LAA and using a series of small incisions—or the application of energy—to create carefully located scarring on the heart. The scars interfere with the transmission of electrical impulses.

One type of maze procedure has long been considered the “gold standard” for treating Afib, but all are complex open-chest surgeries.
What is the LARIAT procedure?

Rather than removing the LAA surgically, the LARIAT procedure closes it off non-surgically, using a loop of suture material. Catheters are used to deliver the suture loop, slip it around the LAA, and tighten it to close off the LAA. This isolates the LAA, potentially reducing its ability to add to the irregular rhythm of the heart. The scar that forms as the area around the suture heals simulates the scars created in non-surgical and surgical maze procedures.
What is the purpose of this study?
This study is being conducted to determine whether the LARIAT procedure can help patients with persistent and/or longstanding persistent Afib when done in addition to catheter ablation.

Patients in the study will be divided into two groups. Each group will receive one of the following treatments:

1. Closing the left atrial appendage with the LARIAT procedure, followed by catheter ablation
2. Catheter ablation only

The LARIAT procedure is currently cleared by the United States Food and Drug Administration (FDA) for use in general surgery, but has not been well-studied for closing the LAA in Afib patients also receiving catheter ablation. Therefore, it is investigational for this specific purpose. Clinical studies of the LARIAT and similar devices suggest it may help reduce the recurrence of Afib.

How can I tell if I am eligible to participate in this study?
If you have persistent Afib or longstanding persistent Afib and want to participate, you will undergo a series of assessments to see if you meet all criteria.
Am I required to participate in this study?
No. Your doctor has recommended it as a potential option for you, based on your medical history. This indicates that you may benefit from it, but you may choose not to participate.

How might closing my LAA in addition to ablation benefit me?
The LAA is a known source of electrical activity that can contribute to Afib. Until now, there has not been a non-surgical method of closing the LAA to isolate the electrical activity.

If I do not have my LAA closed and only have an ablation, will I continue to have Afib?
You may continue to have Afib regardless of the study group you are placed in, but recent studies are encouraging. Catheter ablation success rates for persistent and longstanding persistent Afib have improved over time, based on a better understanding of the conditions; on new techniques and technology; and on more doctor experience.

What will I be asked to do for this study?
The study consists of four phases: Screening, randomization, treatment procedures for Afib, and follow-up.

Screening
In this phase, it will be determined whether you are a good fit for this study. You will be asked about your medical history, current health and medications. You will have common medical tests, which may include CT scans, electrocardiogram tests (including holter monitoring), a seven-day event recorder test, a blood test and a pregnancy test.

If the screening tests determine that you are not eligible for the study, you will not go through the additional three phases. Even if you pass the screening tests, you don’t have to participate in the study if you decide you don’t want to.

Randomization
If you meet all eligibility requirements, you will be randomly assigned to receive either: (a) the LARIAT procedure plus catheter ablation or (b) catheter ablation only (you will not receive the LARIAT procedure).

The chance of receiving one treatment versus the other is random, but more than two-thirds of study participants will receive the LARIAT procedure.
Procedures to treat Afib

If you are assigned to the LARIAT plus catheter ablation group, you will have ultrasound images taken of your heart. If the ultrasound does not show anything that would make you unsuitable for the study, you will have the LARIAT procedure first and the catheter ablation procedure at a later time.

All participants in both groups will receive the catheter ablation.

For detailed descriptions of catheter ablation and the LARIAT procedure, please talk to your physician and refer to the aMAZE Trial patient informed consent form.

Follow-up

This phase of the study is especially important. To evaluate the effect of the LAA closure and/or catheter ablation, study doctors will need to perform a variety of follow-up tests and track your symptoms. Details are provided on next page.

What should I expect immediately after a procedure to treat Afib?

Your physician can describe how you may feel after each type of procedure. After a procedure, you may be prescribed medication to help manage your recovery.

How long will I be in the study?

The length of time you will spend in the study will depend on which group you are in:

LARIAT Plus Catheter Ablation group: 13–14 months
1. Within a month of being assigned to this group, you will have the LARIAT procedure. The procedure will take place under general anesthesia. You will leave the hospital when your doctor feels you are ready to go home.
2. One month later, you will have a follow-up visit with your doctor.
3. Within a month after that follow-up visit, you will have the catheter ablation. You may stay in the hospital overnight so your doctor can monitor your progress.
You will have additional follow-up visits one month, three months, six months and one year after your catheter ablation. Your one-year follow-up will include an echocardiogram.

Catheter Ablation Only group: 12 months
Within a month of being assigned to this group, you will have the catheter ablation. You may stay in the hospital overnight so your doctor can monitor your progress.
You will have follow-up visits at one month, three months, six months and one year after your catheter ablation.
What are the follow-up visits for?
Your follow-up visits are very important. Not only do they allow doctors to track your progress and make sure you are healthy, they also provide the information that will determine the study’s results. Your follow-up visits can ultimately help others with Afib in the future.

These follow-up visits may include:
• A limited physical exam, including an assessment of any illnesses, rehospitalizations or other events related to your heart condition that have occurred
• Questions about your Afib symptoms since your last study visit
• ECG and blood tests
If you still have Afib, you may be asked to begin taking new medication or different doses of your current medication. You may also have a cardioversion treatment.
At the visits six months and one year after your ablation, you will be asked to wear a holter monitor for 24 hours. The monitor will track and record your heart rhythm to see if your Afib has returned.

What company makes the LARIAT?
The LARIAT device is made by SentreHEART, a privately-held medical device company specializing in catheter innovations and suture delivery technology. For more information, please visit www.sentreheart.com.

Where can I get more information?
Your doctor may be able to answer specific questions you might have, but you can also find out more about the study and what to expect by reading the patient informed consent form you were given along with this booklet.
To learn more about this study and clinical trials in general, please visit https://clinicaltrials.gov.
To learn more about Afib, visit http://www.stopafib.org.
REFERENCES:

Clinicaltrials.gov Identifier: NCT02513797
aMAZE is an FDA-approved trial – U.S. FDA IDE# G150107
CAUTION Investigational study device.
Limited by Federal law to investigational study use.
PRM-0031 Rev A