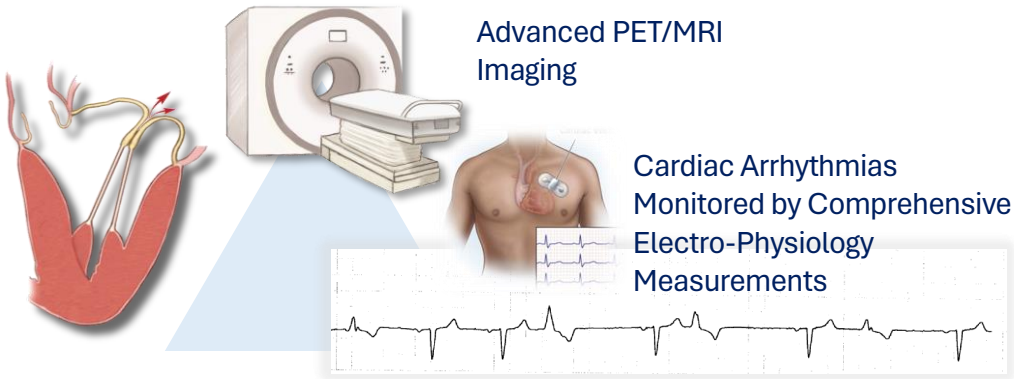
Icahn School of Medicine at Mount Sinai

PET/MRI Imaging of Mitral Valve Prolapse

A Research Study About Arrhythmic Mitral Valve Prolapse (MVP) at the Icahn School of Medicine at Mount Sinai



Background and Goals of the Study

- Mitral valve prolapse (MVP) is the most common valve abnormality.
- Some people with MVP are at a greater risk of cardiac arrhythmias that in some cases can lead to dangerous (malignant) arrhythmias and sudden death.
- The risk of dangerous life-threatening arrhythmias may not depend on severity of Mitral Regurgitation.
- Strategies to determine the risk of these malignant arrhythmias are not well established.
- Scar (fibrosis) in the heart near the Mitral Valve has been noted in those with MVP who have suffered malignant arrhythmias and sudden cardiac arrest.
- Recently, inflammation in the heart has been recognized as an important component of developing life-threatening arrhythmias in MVP.
- This study aims to use advanced imaging of inflammation and scar tissue in the heart and comprehensive rhythm monitoring over 5 years to help better understand the causes of arrhythmias in MVP and develop better strategies to estimate risk.
- This study could help develop better ways to recognize and prevent malignant arrhythmias and sudden death in at-risk patients.

Who can participate

- The study aims to recruit 400 patients overall, age 20 years or above, with diagnosed MVP.
- In one group, patients will also have mitral valve regurgitation and a history of premature ventricular contractions (PVCs). You do not need to have severe mitral regurgitation to qualify.
- In another group, patients will already be scheduled for Mitral Valve repair surgery as part of their clinical care. The study will aim to determine how inflammation in the heart and cardiac arrhythmias change after MV repair.
- The cost of the sophisticated imaging studies and blood tests/biopsies will be paid for by the research grant. Monetary compensation up to $750 is available for the time and effort required to participate.
- All study tests will be done at Mount Sinai Hospital with additional at-home heart rhythm monitoring. If you receive care from a Mount Sinai doctor, participation in the study can be done alongside your lar care.
- Participation in the study will not affect your ability to receive care from Mount Sinai.
- For more information about the study and to find out if you qualify, please contact the Study Coordinators or Study Investigators listed on the last page of this brochure).

IRB Approved

Effective Date: 8/13/2024
End Date:8/12/2025

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Approved by the Mount Sinai IRB (STUDY 23-00820)

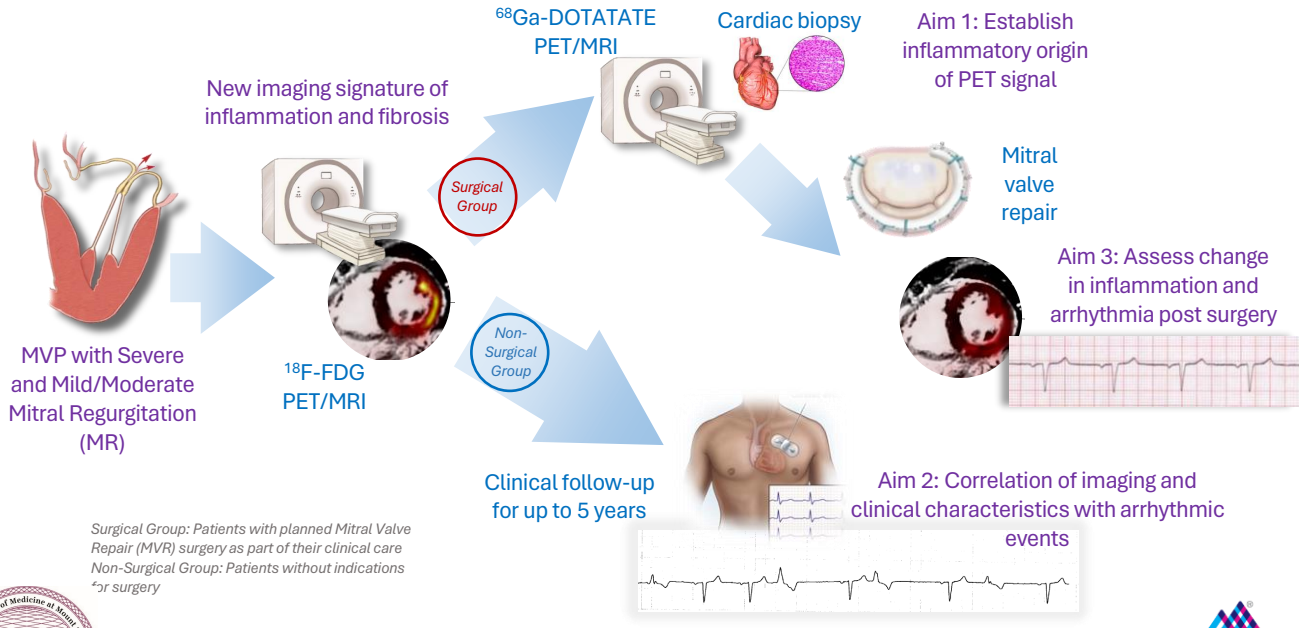
What Are the Aims of the Study and How is the Study Designed?

The study will involve two groups of participants. The study tests involved will be different for the two groups. If you are already going to undergo Mitral Valve Repair surgery as part of your clinical care, you will be in the *Surgical Group* if you have MVP without any indication for surgery you will be in the *Non-Surgical Group*. Both groups will have advanced PET/MRI imaging and additional study tests (detailed on the next page).

The Aims of the Study are:

1. To establish that inflammation in the heart is present in arrhythmic MVP. To do this, participants in the *Surgical Group* will undergo two special kinds of PET/MRI and have a tiny piece of heart tissue taken (a biopsy) during your planned MV repair surgery to confirm that all the imaging markers are related to inflammation.
2. To see how well the advanced PET/MRI imaging and comprehensive heart rhythm monitoring predicts the development and progression of cardiac arrhythmias. To do this, participants in the *Non-Surgical Group* will undergo a single PET/MRI imaging study and then annual heart rhythm monitoring for up to 5 years. At the end of the study, imaging will be correlated with cardiac arrhythmias and events based on the rhythm monitoring.
3. To see how mitral valve repair changes inflammation and arrhythmias. To do this, participants in *Surgical Group* will undergo repeat PET/MRI imaging and heart rhythm monitoring a year after planned MV surgery.

Study Diagram



Surgical Group: Patients with planned Mitral Valve Repair (MVR) surgery as part of their clinical care
Non-Surgical Group: Patients without indications for surgery

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What's Involved and When?

Participants undergoing MV Repair surgery

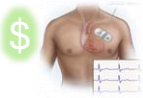
AT ENROLLMENT

PET/MRI imaging

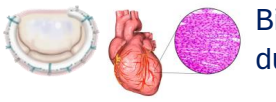
Blood tests

PET/MRI imaging

3D echo-cardiography plus ECG

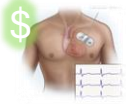


14-day heart rhythm monitor



Biopsy of heart muscle during planned surgery

AFTER 1 YEAR



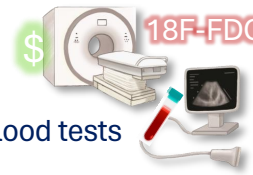
AFTER 4 YEARS

Chart review

Participants not undergoing surgery

AT ENROLLMENT

PET/MRI imaging



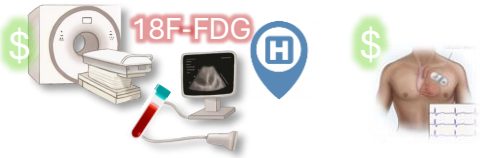
Blood tests

3D echo-cardiography plus ECG

14-day heart rhythm monitor

AFTER 1 YEAR

AFTER 2 YEARS



AFTER 3 YEARS

AFTER 4 YEARS

Chart review

Special considerations:

- Most tests will be completed at the hospital and some at home
- Tests will be scheduled together to make as few hospital visits as possible but final schedules can be adjusted to fit your schedule.
- PET imaging involves a small amount of radiation exposure, about the same as background radiation in 1 year. You can not participate if you are pregnant or nursing.
- FDG PET imaging requires fasting for 12 hours prior to the study, and consumption of a high fat/protein and low carbohydrate diet prior to that.
- DOTATATE PET imaging and a biopsy test during MV repair surgery will be used to validate the findings from the more common FDG PET imaging technique.
- $150 will be provided after completion of certain tests to compensate participants for time and effort.

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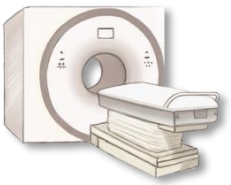
What Are the Study Tests?

PET/MRI imaging



Positron Emission Tomography (PET) is a type of scan that produces detailed pictures of the inside of the body using a radioactive tracer that is injected into the bloodstream. MRI uses a magnetic field and radio waves to produce detailed pictures of the body's organs and structures. In this study the MRI scanner is part of the same machine as the PET scanner (PET/MRI). Both PET and MRI imaging are safe, painless, and non-invasive tests. PET and MRI are used daily by hospitals around the world to image the heart.

Before the PET scan, a small amount of radioactive tracer (^{18}F-FDG or ^{68}Ga-DOTATATE) is given through a vein (IV). The needle is most often inserted on the inside of your elbow. The tracer travels through your blood and collects in organs and tissues. This helps the researchers see certain areas more clearly. You will need to wait as the tracer is absorbed by your body. This takes about 1 hour. Then, you will lie on a narrow table that slides into a large tunnel-shaped scanner while the scanner makes 3D pictures of the body.

The radiation of one test is about the same as from background radiation in one year. Those who are pregnant or nursing can not participate.

For MRI a different tracer called Gadolinium is injected during the scan to help make pictures of the heart.

You must lie still during the test. Too much movement can blur images and cause errors. For some of the MRI pictures you will be asked to hold your breath for 8-12 seconds at a time while the scanner takes a picture of your heart. The technologist will coach you through the procedure. PET/MRI imaging will take 60-90 minutes.

For ^{18}F-FDG PET imaging, it is necessary for you to follow a special high fat/protein low-carbohydrate diet for 24 hours prior to the scan, and for you to fast for 12 hours prior to the scan. If you are diabetic you may be required to alter your insulin doses. Additional guidance will be provided.

18F-FDG

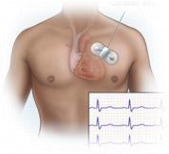
vs.

68Ga-DOTATATE

For participants in the *Surgical Group*, you will undergo PET/MRI with two different tracers. Both ^{18}F-FDG and ^{68}Ga-DOTATATE target inflammation in the heart but ^{68}Ga-DOTATATE is much more specialized and is being used to validate the findings from the more common tracer ^{18}F-FDG.

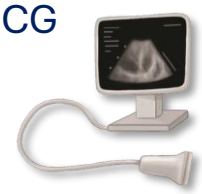
What Are the Study Tests?

14-day heart rhythm monitor



An extended ambulatory event monitor (Holter monitor) test is similar to an ECG test but you will be asked to wear the monitor for 14 days. There are fewer electrical pads and the monitor is stuck to your chest.

3D echo-cardiography plus ECG



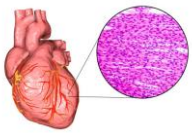
An echocardiogram is an ultrasound to look at the condition of your heart. An ultrasound probe with gel will be placed on the surface of your chest to obtain images of your heart. This test is done in the doctor's office and takes about 30 minutes.

A 12 lead electrocardiogram (ECG) is a test that uses electrical pads placed on your chest to measure the functioning of your heart and to test for arrhythmias. This test is done in the doctor's office and takes about 30 minutes.

Blood tests

At the time of your imaging tests, blood will be collected to test for specific enzymes to check the function of your organs such as Inflammatory Cytokines, ESR, CRP, Troponin, and BNP and other markers related to MVP and your risk of arrhythmic events. The blood tests will also be used to look for genetic markers of risk for MVP. About 50 ml (10 tbsp) of blood will be taken. Some blood will be stored for additional tests related to inflammation or that are relevant to MVP.

Biopsy of heart muscle during planned surgery



At the time of your planned Mitral Valve Surgery (which is part of your clinical care and not part of the research), a tiny amount of heart tissue (biopsy) will be collected by your heart surgeon. Locations for biopsy will be planned by the lead researcher and the study team prior to surgery based on imaging data by PET/MRI scans. Specimens will be collected using standard surgical techniques. The surgeon will only perform the biopsy if it is safe to do so. The biopsy specimen will be sent to the Mount Sinai Institutional Biorepository and Pathology CoRE Lab for tissue processing and storage.

Who Can I Contact About The Study?

For more information about the study please contact any of the study researchers or coordinators.

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