



REPAIR MR

T R I A L



PATIENT INFORMATION GUIDE

A Clinical Trial for People with Mitral Regurgitation

This brochure describes a clinical trial evaluating the use of transcatheter mitral valve repair (TMVr) for the treatment of mitral regurgitation. Please use this information, and consult your doctor to determine if participation in this clinical trial may be right for you.

The REPAIR MR Clinical Trial

The purpose of the REPAIR MR Clinical Trial is to study the Abbott MitraClip™ Transcatheter Mitral Valve Repair (TMVr) system in patients with severe mitral regurgitation who are at moderate surgical risk and whose mitral valve has been determined to be suitable for correction by mitral valve repair surgery.

Approximately 500 subjects will be studied at up to 60 medical centers in the United States, Canada and Europe. A team of medical experts will monitor patients who enroll in the REPAIR MR Clinical Trial.

Patients will play an important role in helping doctors evaluate TMVr as an option for patients with severe mitral regurgitation who are candidates for surgery.

The REPAIR MR Clinical Trial is a randomized study. This means patients have a 50/50 chance of receiving either a surgical repair or TMVr.

Regardless of which procedure you receive, the doctors and hospitals that participate in the REPAIR MR Clinical Trial specialize in mitral valve therapy.



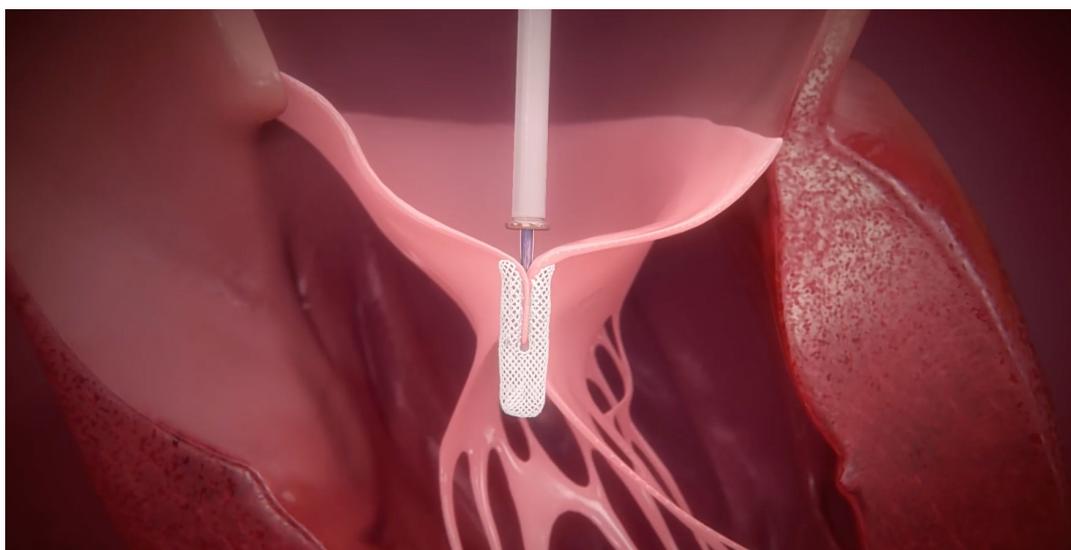
The Abbott MitraClip™ Transcatheter Mitral Valve Repair

Mitral Valve Repair Treatment Options In The Repair MR Clinical Trial

Today there are two options to repair your mitral valve: surgical mitral valve repair and TMVr.

Surgical mitral valve repair. Most surgical mitral valve repair are performed through an incision across the the breast bone, or sternum. Occasionally surgical mitral valve repair can be performed through smaller incisions. During the procedure, the surgeon repairs the diseased mitral valve.

Transcatheter mitral valve repair (TMVr). During TMVr, a MitraClip™ implant is inserted through a vein into the heart. The MitraClip™ implant grasps the defective mitral valve leaflets, closes the center of the mitral valve and reduces mitral regurgitation. TMVr is performed without an incision to the patient's chest and the patient does not need to be on a heart-lung machine. [See how the MitraClip™ therapy works at this link.](#)



The MitraClip™ Implant Grasping Mitral Valve Leaflets



Are You a Candidate?

If you agree to participate in the REPAIR MR Clinical Trial, you will be screened (evaluated). Your screening may include a physical exam, an echocardiogram (Echo), blood tests and a review of your medical history. It will be determined if you are able to participate in the study based on the results of the screening tests and procedures. You may be eligible for this study if:

- You have been diagnosed with mitral regurgitation
- You are willing and able to receive the clinical trial procedures and participate in follow-up monitoring.

Your research coordinator will discuss the full list of criteria for participating in the clinical trial with you.

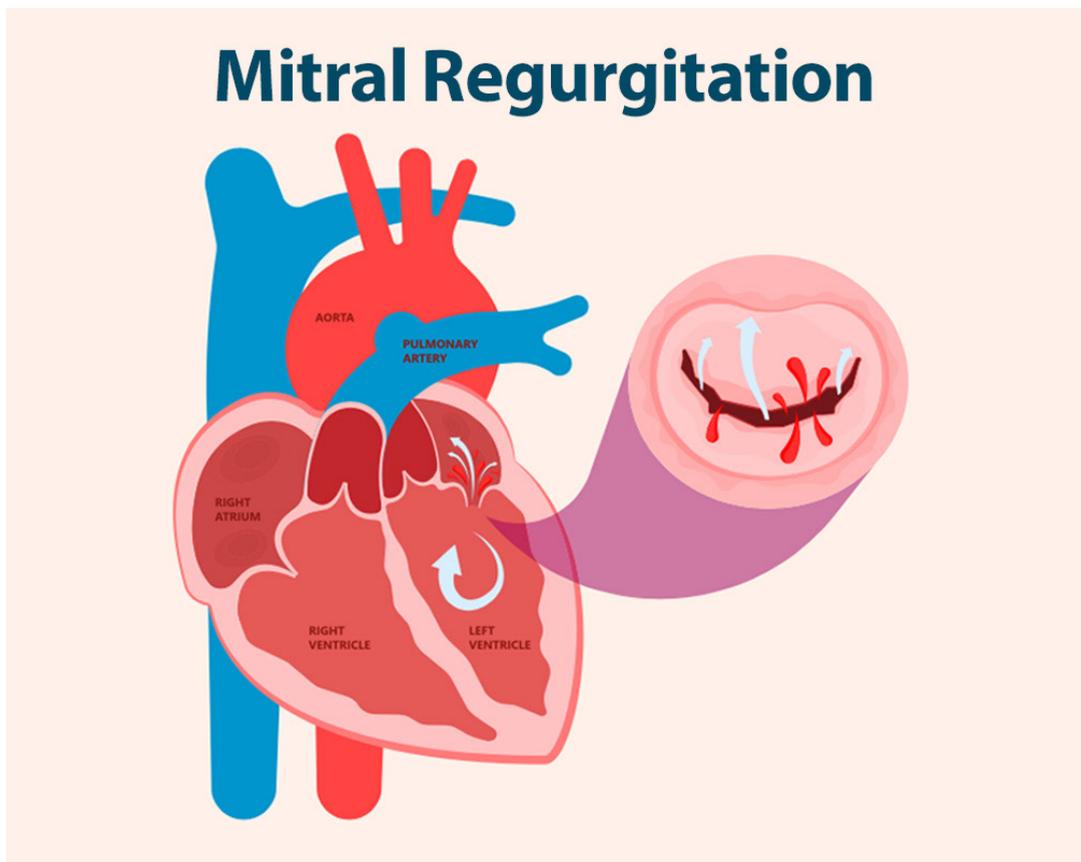
About Mitral Regurgitation

The mitral valve is one of four valves in your heart that opens to let blood flow forward and closes to prevent the backflow of blood.

Mitral regurgitation happens when blood leaks backward across the valve because your mitral valve does not close tightly.

Mitral regurgitation may cause symptoms including shortness of breath, chest pain, heart palpitations and fatigue. Patients with mitral regurgitation may also be asymptomatic (without symptoms).

Over time, mitral regurgitation can cause the heart to enlarge, weaken, and ultimately result in heart failure and death.



Potential Benefits Of The REPAIR MR Clinical Trial

You may or may not experience any direct benefit from this clinical trial.

The potential benefit from undergoing screening tests and procedures is that you will have undergone a thorough examination of your medical condition and you may have a better understanding of available therapies.

Potential benefits of the clinical trial procedures may include improvement in the symptoms related to your mitral regurgitation. Repairing your mitral valve may provide both short- and long-term relief of your symptoms, improved mitral valve function, and improved cardiac function that could potentially increase your life expectancy and improve your quality of life.

Potential benefits of TMVr include a less invasive procedure, shorter procedure time, less anesthesia, shorter hospital stays, and faster recovery compared to heart surgery for mitral valve repair. TMVr is proven to be safe with experience of over 100,000 implants worldwide.

It is possible that you will receive no direct benefit from this clinical trial, but future patients may benefit from your participation.

Potential Risks Of The Clinical Trial

Risks of having your mitral valve repaired include death, stroke, and major bleeding. As the clinical trial progresses, you will be informed of new trial results that may affect your willingness to remain in the clinical trial. Your doctor and/or research team will speak to you about these risks and other potential complications and answer any questions you may have.

Questions To Ask Your Doctor

To help you learn more about this clinical trial, here are some questions you may want to ask your doctor:

- Am I a candidate for the REPAIR MR Clinical Trial?
- What tests do I need?
- What are the possible risks, side effects, and benefits of participating in this clinical trial?
- How long will I be in the hospital?
- What will the recovery be like for TMVr compared to open heart surgery?
- What restrictions and/or medications, if any, would I be on after the procedure?
- How frequently will I need to have follow-up visits?
- How long will the study last?





Where Can I Learn More About The REPAIR MR Clinical Trial?

For more information on the REPAIR MR Clinical Trial and to see a full list of clinical trial sites you can contact, please visit ClinicalTrials.gov.

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