

Get treatment for
mitral regurgitation
and help others like you

 THE
CLASP IID/IIF
TRIAL



Talk to your doctor or a research coordinator
to find out if this clinical trial is right for you

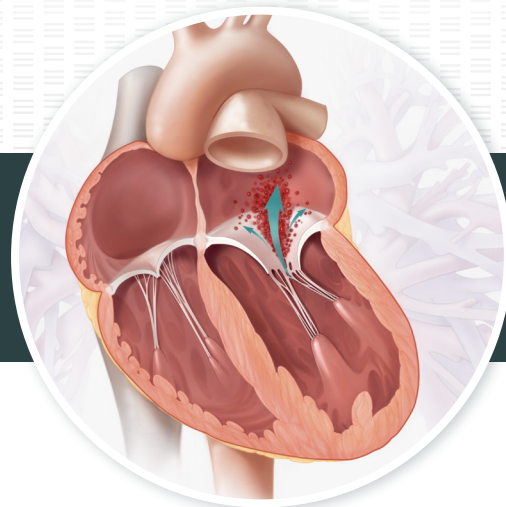
What is mitral regurgitation?

If you or a loved one have mitral regurgitation (MR), know you're not alone and you have options when it comes to treatment. But first, let's understand what MR is.

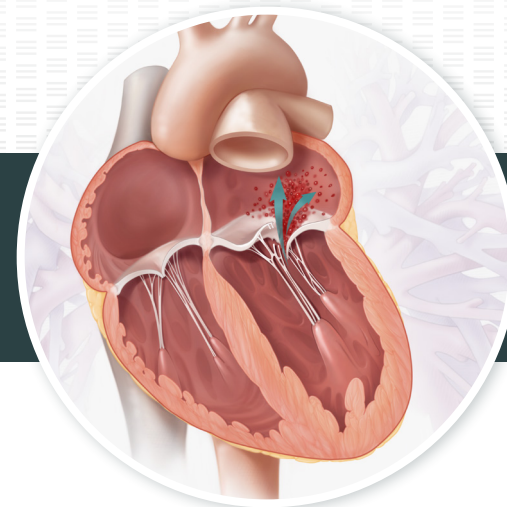
Mitral regurgitation occurs when the mitral valve in your heart doesn't close all the way. This lets blood leak back into your heart and makes it difficult to pump enough blood through your body. It can make you feel tired or short of breath, and lead to heart failure, if left untreated.

Know your type of MR:

Check which one you have below



- Functional mitral regurgitation (FMR)** occurs when the valve has been stretched and its leaflets don't close tightly, causing blood to leak back into the heart.



- Degenerative mitral regurgitation (DMR)** usually occurs due to a structural problem with the valve's leaflets that prevents them from closing properly, causing a large amount of blood to flow backwards.

Mitral regurgitation can be treated by repairing or replacing the mitral valve.

Getting treated for MR could make a difference for your heart and quality of life

What are my MR treatment options?

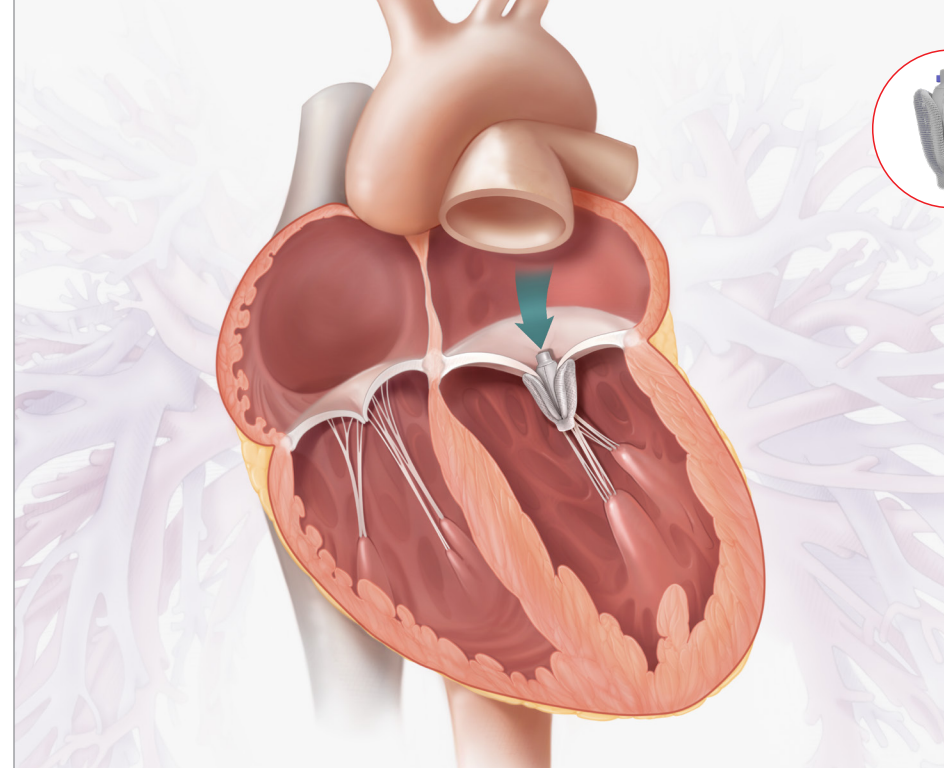
Transcatheter mitral valve repair provides a less-invasive alternative to open heart surgery for eligible patients

There are a few different ways to treat MR

Two common treatment methods involve repairing or replacing the mitral valve in order to prevent backward leakage and help blood flow properly.

1 **Open heart surgery** involves making an incision in the chest and either repairing or replacing the mitral valve. While open heart surgery might be an effective treatment, your doctor may suggest an alternative depending on your circumstances.

2 **Transcatheter mitral valve repair** procedure is a less invasive method performed through a small incision in the leg. Your doctor places a thin tube through a large vein in your leg to reach your heart, and then implants a small device to repair the mitral valve.



Edwards PASCAL transcatheter valve repair system

Actual size

The CLASP IID/IIF clinical trial studies the PASCAL repair system, a device designed to repair the mitral valve with NO open heart surgery

Interested? Ask your doctor if you're eligible to enroll.

What is the CLASP IID/IIF clinical trial?

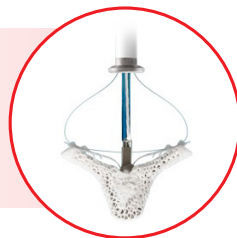
- This trial will evaluate a new device designed to treat MR by repairing the mitral valve using a transcatheter procedure (no open heart surgery)
- You will receive one of two therapies, the PASCAL system, which is under investigation in this study, or MitraClip, a commercially available treatment option
- Your health will be monitored throughout the clinical trial and after implantation of the device. This will require you to come in for several follow-up visits over a 5-year period.
- This clinical study will allow doctors to understand how the PASCAL repair system works in patients like you

The trial is intended to show the PASCAL repair system works just as well as a currently available FDA-approved device



The PASCAL system is an investigational device designed to repair the mitral valve

The MitraClip system approved by the FDA to treat MR



What to expect?

- Depending on your diagnosis (DMR or FMR), you will be enrolled in either the CLASP IID or CLASP IIF group
- Patients will then be randomly separated further into two groups, one of which will be treated with the PASCAL repair system and the other with the FDA-approved MitraClip system

Remember, regardless of which group you are assigned, you will be treated for MR through a minimally invasive transcatheter procedure

What will it cost?

- If not the standard of care, certain tests and procedures that are done in the study or required by the study protocol will be covered by Edwards Lifesciences, the sponsor of the study
- You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments that would be billed to you or your health insurance provider

Will I be compensated?

You will receive **either**:

- 1 **A \$50 stipend** for EACH completed follow-up visit required by the study
- OR**
- 2 **Reimbursement for actual travel expenses incurred up to \$200** for each completed follow-up visit required by the study

Please note that you are eligible for either the stipend or the travel reimbursement, but not both. Some clinical trial sites only offer one form of compensation. Consult your doctor for more details.

Interested in joining the CLASP IID/IIF clinical trial?

Here's how to get started

Are you a candidate?

You may be eligible for this trial if you meet these key criteria:

- 1 You are 18 years of age or older

AND

- 2 You have severe **degenerative mitral regurgitation** and are considered prohibitive risk for mitral valve surgery by your heart team
OR
You have severe **functional mitral regurgitation** with stable heart failure medications as determined by your heart team

Ask your doctor or research coordinator for the full list of criteria.

If you choose to participate, you will be asked to complete health and imaging assessments to ensure you still meet the criteria to continue in the clinical trial.

Why participate?

You have the opportunity to be treated with one of two devices designed to treat mitral regurgitation.

Treating mitral regurgitation early is key to maintaining your heart health

Talk to your doctor to determine if this clinical trial is right for you. Since enrollment in the trial requires submitting imaging results, act soon to use your latest assessments before they expire.

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Questions to ask your doctor before joining the clinical trial

Write down any additional questions to ask your doctor in the space provided

- How can this clinical trial help me?
- Do you think transcatheter mitral valve repair is an option for me?
- What testing will I have to do during the trial?
- Will I be able to take the medications I take now?
- What are the risks of participating?
- _____
- _____

Notes:

Treating mitral regurgitation early is key to maintaining your heart health

Talk to your doctor to determine if this clinical trial is right for you.

Place your healthcare professional's business card here or fill in their contact information

Name: _____

Phone: _____

Email: _____

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Edwards Lifesciences is the sponsor of the CLASP IID/IIF trial.

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