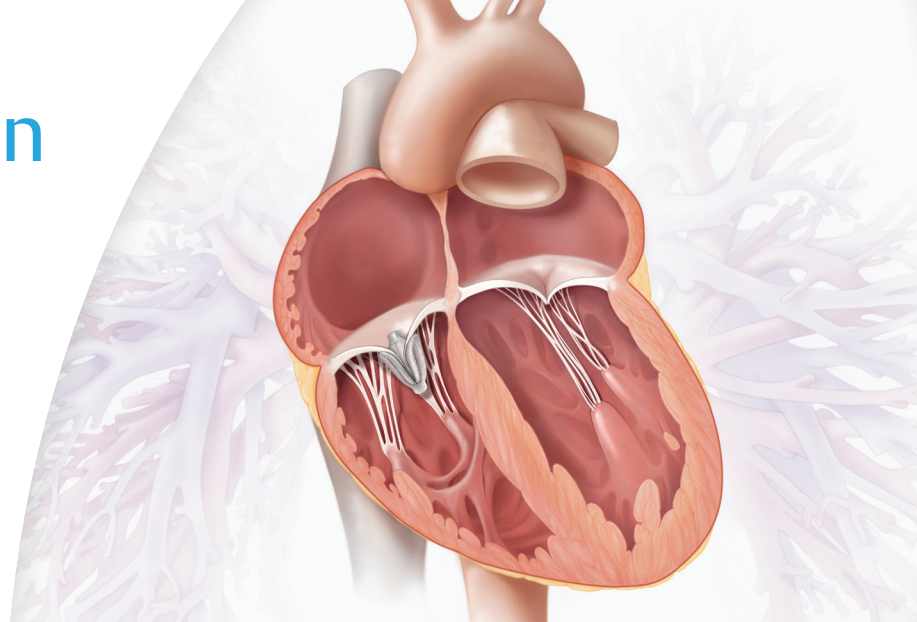


A treatment option
being studied
for **tricuspid
regurgitation**

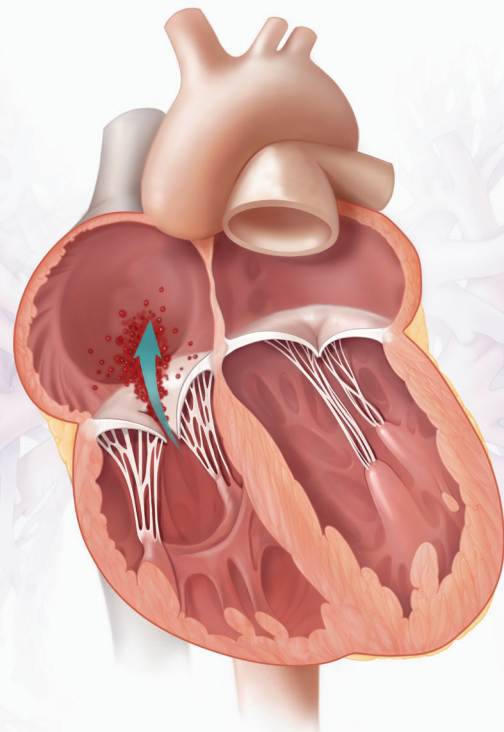
 THE
CLASP II TR
TRIAL



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

What is tricuspid regurgitation?

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



Tricuspid regurgitation can impact your quality of life and can also lead to heart failure, which can lead to death. In spite of the serious risks, there are very few treatment options for patients like you who are living with TR.

Tricuspid regurgitation occurs when the tricuspid valve on the right side of the heart doesn't close all the way, usually because the **valve has been stretched** and its leaflets don't close tightly. This allows blood to flow back into your body, which can cause shortness of breath and swelling in the extremities, and can lead to heart failure, if left untreated.

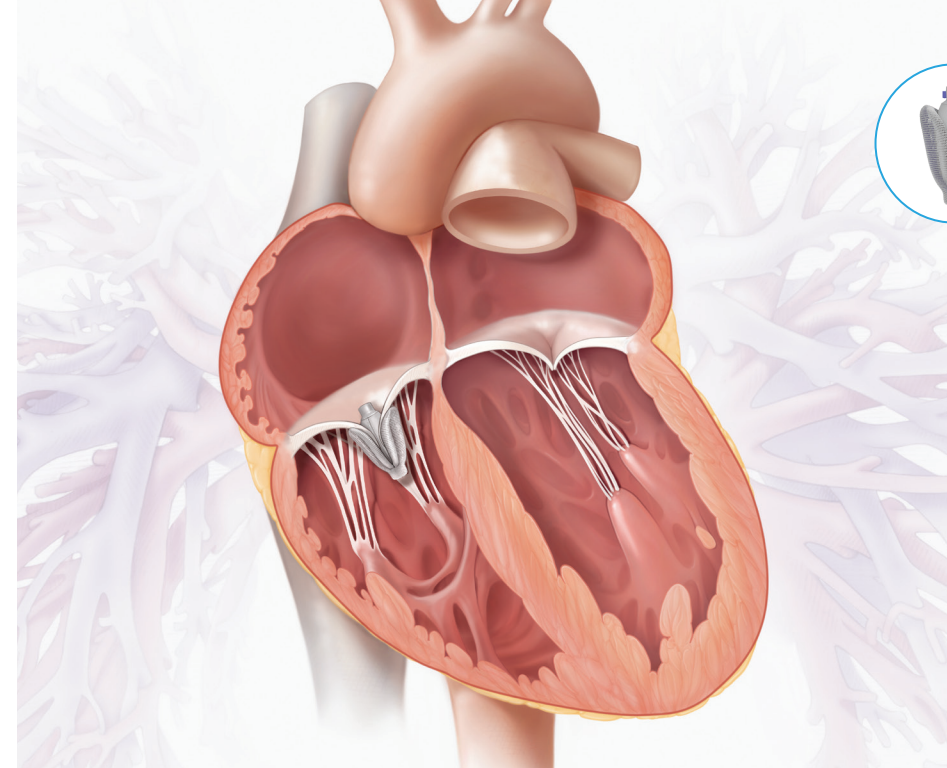
TR has serious health risks if left untreated

What are my TR treatment options?

Treatment for TR depends on the underlying cause and severity of the disease.

There are a few different ways to treat TR

	Medication	Open heart surgery	Transcatheter tricuspid valve repair being studied
Treats the root cause of TR	✗	✓	<i>currently being evaluated</i>
Less invasive	✓	✗	✓



Edwards PASCAL transcatheter valve repair system
Actual size

The CLASP II TR clinical trial studies the PASCAL system, a device designed to repair the tricuspid valve through a small incision in the leg instead of open heart surgery
Interested? Ask your doctor if you're eligible to enroll.

What is the CLASP II TR clinical trial?

This trial is studying the treatment of TR with the PASCAL transcatheter valve repair system

- This trial will examine an innovative device designed to repair the tricuspid valve and reduce the amount of leakage using a transcatheter procedure (no open heart surgery)
- During this clinical trial, you will either be treated with medication alone, or you will get a valve repair using PASCAL in addition to being treated with medication
- 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 system works in patients like you
- The trial is intended to evaluate the safety and efficacy of the PASCAL system when paired with medication, compared to treatment with medication alone

What will it cost?

- The tests or procedures required by the research trial that would not otherwise be part of your standard care will be covered by Edwards Lifesciences, the Sponsor of this trial
- 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



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

Interested in joining the CLASP II TR clinical trial?

Here's how to get started

Are you a candidate?

You may be eligible for this trial if you're an adult and you have severe and symptomatic tricuspid regurgitation, 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 meet the criteria to continue in the clinical trial.

Why participate?

Problems with the tricuspid valve often go untreated, but this study may unveil critical information about the PASCAL repair system, a treatment option for tricuspid regurgitation. Your participation may assist in better understanding treatment options for tricuspid regurgitation and may help the treatment of other patients in the future.



Consider taking part in the CLASP II TR clinical trial

If you're interested in participating in this clinical trial, talk to your doctor today.

 THE
CLASP II TR
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Ask your doctor for more information about the clinical trial

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

- Do you think transcatheter tricuspid 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:

Talk to your doctor to determine if you are eligible to participate in this clinical trial

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

Name: _____

Phone: _____

Email: _____

CAUTION – Investigational device. Limited by Federal (or United States) law to investigational use. This device is not available for marketing or commercial sale in the United States. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences is the Sponsor of the CLASP II TR trial.

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