A treatment option being studied for tricuspid regurgitation

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.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Open heart surgery</th>
<th>Transcatheter tricuspid valve repair or replacement</th>
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<tbody>
<tr>
<td>Medications are used to control symptoms.</td>
<td>Surgery on the tricuspid valve is occasionally done when there is some other surgery being planned on your heart.</td>
<td>A thin tube would be placed through a vein in your leg to reach your heart and either repair or replace the tricuspid valve. This is a new treatment being evaluated.</td>
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- Treats the root cause of TR: ✗ ✓ ✓
- Less invasive: ✓ ✗ ✓

The TRISCEND II clinical trial studies the EVOQUE system, a tricuspid valve replacement system with no open heart surgery. Interested? Ask your doctor if you’re eligible to enroll.

Edwards EVOQUE tricuspid valve replacement system
What is the TRISCEND II clinical trial?

This trial is studying the treatment of TR with the EVOQUE transcatheter valve replacement system.

- This trial will examine an innovative tricuspid valve replacement system 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 replacement using the EVOQUE system in addition to being treated with medication.
- Your health will be monitored throughout the clinical trial and after the valve replacement. 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 EVOQUE system works in patients like you.
- The trial is intended to evaluate the safety and efficacy of the EVOQUE 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.
Interested in joining the TRISCEND II clinical trial?

**Are you a candidate?**

You may be eligible for this trial if you’re an adult and you have severe or greater, 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 a new solution. Your participation may assist in better understanding treatment options for tricuspid regurgitation and may help the treatment of other patients in the future.

Here’s how to get started

Consider taking part in the TRISCEND II clinical trial

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

☐ ____________________________________________

☐ ____________________________________________

☐ ____________________________________________

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Notes:

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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: ______________________________