

Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial

NCT04097145

Status	RECRUITING
Phase	Not Applicable
Sponsor	Edwards Lifesciences
Enrollment	870 participants

Key Eligibility Criteria

Inclusion (6)

- Eighteen (18) years of age or older
 - Despite medical therapy, per the local Heart Team, patient has signs of TR, symptoms from TR, or prior heart failure hospitalization from TR.
 - Severe or greater tricuspid regurgitation
 - New York Heart Association (NYHA) Class II-IVa or heart failure hospitalization in the prior 12 months
 - Patient is at an intermediate or greater estimated risk of mortality with tricuspid valve surgery as determined by the cardiac surgeon with concurrence by the local Heart Team
- ... and 1 more (see full listing online)

Exclusion (30)

- Tricuspid valve anatomy not evaluable by TTE or TEE
 - Tricuspid valve anatomy precludes proper device deployment and function
 - Patient with refractory heart failure requiring, advanced intervention (i.e. patient has or will need left ventricular assist device, or transplantation) (ACC/AHA Stage D heart failure)
 - Presence of trans-tricuspid pacemaker or defibrillator leads which meet one of the following:
 - Would prevent proper TR reduction due to interaction of the lead with the leaflets
- ... and 25 more (see full listing online)

Locations (79 total)

Banner University Medical Center Phoenix, Phoenix, Arizona, United States
Tucson Medical Center Healthcare, Tucson, Arizona, United States
University of California, Irvine, Irvine, California, United States
... and 76 more locations

<https://clinicaltrials.gov/study/NCT04097145>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at ClinicalTrials.gov. Generated by ClinicalTrialsFinder.org.