

# Safety and Feasibility Study: Transcatheter Valve Repair in Severe Symptomatic Functional Tricuspid Regurgitation

NCT07140562

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Tangent Cardiovascular Inc.
Enrollment	25 participants

## Key Eligibility Criteria

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### Inclusion (6)

- years old at the time of consent
- Symptomatic functional tricuspid regurgitation (without co-existing degenerative disease) despite being adequately treated with optimal medical therapy by the Local Heart Team for at least 30 days prior to the study consent
- Severe, massive or torrential functional tricuspid regurgitation, as determined by qualifying transesophageal echocardiogram (TEE) and/or transthoracic echocardiogram (TTE) using the 5-grade classification
- TEE imaging confirms adequate visualization of valve for TR quantification and procedural guidance
- The Local Heart Team determines the candidate is suitable for transcatheter tricuspid valve repair
- ... and 1 more (see full listing online)

### Exclusion (27)

- Estimated life expectancy of less than 12 months
- Systolic pulmonary artery pressure (sPAP)  $\geq 70$  mmHg as assessed by TTE or right heart catheterization
- Acutely decompensated, defined as hypotension with SBP  $< 90$  mmHg, use of hemodynamic support devices or inotropes or uncontrolled arterial hypertension with SBP  $> 180$  mmHg within 30 days of the study procedure
- Severe COPD dependent on home oxygen or chronic home oxygen use
- Echocardiographic evidence of severe right ventricular dysfunction
- ... and 22 more (see full listing online)

## Locations (1 total)

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Sanatorio Italiano, Asunción, Paraguay