TTVR Early Feasibility Study

NCT04433065

Status	RECRUITING
Phase	Not Applicable
Sponsor	Medtronic Cardiovascular
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (7)

- Heart Team agrees that patient is deemed symptomatic despite medical therapy (including obligatory diuretic) and a candidate for bioprosthetic tricuspid valve replacement
- Subject is at an intermediate or greater estimated risk of mortality with tricuspid valve surgery as determined by the local Heart Team
- Subjects with severe symptomatic primary and / or secondary tricuspid regurgitation determined by the Echocardiography Core Lab assessment of a qualifying transthoracic echocardiogram (TTE) and transesophageal echocardiogram (TEE)
- New York Heart Association (NYHA) Function Class II or greater
- Subject anatomically suitable for the Intrepid TTVR delivery system including transfemoral access

... and 2 more (see full listing online)

Exclusion (9)

- Estimated life expectancy of less than 24 months due to associated non-cardiac co-morbid conditions
- Anatomic contraindications for Intrepid™ TTVR (e.g., annular dimensions)
- Evidence of intracardiac mass, inferior vena cava, or femoral venous mass or thrombus
- Implanted with venous stents (iliac and/or femoral) or inferior vena cava (IVC) filter or congenital abnormalities of the IVC that would preclude ability for transfemoral access of delivery system
- Echocardiographic evidence of severe right ventricular dysfunction

... and 4 more (see full listing online)

Locations (20 total)

University of Alabama at Birmingham (UAB) Hospital, Birmingham, Alabama, United States
Abrazo Arizona Heart Hospital, Phoenix, Arizona, United States
Cedars Sinai Medical Center, Los Angeles, California, United States
... and 17 more locations