VenusP-Valve Pivotal Study (PROTEUS STUDY)

NCT06010563

Status	RECRUITING
Phase	Not Applicable
Sponsor	Venus MedTech (HangZhou) Inc.
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (8)

- Weight e25kg (55 lbs.)
- Age e 12 years olds
- Patients have a dysfunctional native RVOT with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography or pulmonary regurgitant fraction e30% as determined by cardiac magnetic resonance imaging) and without significant pulmonary stenosis (significant pulmonary stenosis is defined as gradient more than 25mmHg) and are clinically indicated for intervention:
- \) For symptomatic patients, fitting the following criteria:
- Severe pulmonary regurgitation measured by echocardiogram or pulmonary regurgitant fraction e30% measured by CMR 2) For asymptomatic patients, including any 2 of the following criteria:

... and 3 more (see full listing online)

Exclusion (17)

- Clinical or biological signs of infection including active endocarditis.
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation.
- Leukopenia, anemia, thrombocytopenia, or any known blood clotting disorder, deemed clinically significant after consultation with Haemato-oncology specialists.
- Inappropriate anatomy for femoral or right internal jugular vein (RIJ) introduction and delivery of the VenusP-ValveTM System.
- RVOT anatomy or morphology that is unfavorable for device anchoring.

... and 12 more (see full listing online)

Locations (1 total)

Venusmedtech of America, Irvine, California, United States