

MASA Valve Early Feasibility Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 0 years to 22 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. At least one of the following: Right Ventricular to Pulmonary Artery mean gradient > 35 mm Hg, moderate or severe Pulmonary regurgitation ($\geq 3+$), or clinical indication for replacement of their native or prosthetic pulmonary valve with a prosthesis.
2. Age < 22 years
3. Patient is geographically stable and willing to return for 1 year follow-up for the trial.
4. Patient's legal guardian should be willing to provide informed consent (IC) at the hospital location where they are being enrolled.
5. The patient, and the patient's parent / legal representative where appropriate, and the treating physician agree that the subject will return for all required post-procedure follow up visits and the subject will comply with clinical investigation plan required follow-up visits.

Exclusion Criteria:

1. Patient is in need of or has presence of a prosthetic heart valve at any other position
2. Patient has a need for concomitant surgical procedures (non-cardiac)
3. Patients with previously implanted pacemaker (including defibrillators) or mechanical valves
4. Patient has an active bacterial or viral infection or requiring current antibiotic therapy (if temporary illness, patient may be a candidate 4 weeks after discontinuation of antibiotics)
5. Patient has an active endocarditis
6. Leukopenia, according to local laboratory evaluation of white blood cell count
7. Acute or chronic anemia, according to local laboratory evaluation of hemoglobin Patients can be transfused to meet eligibility criteria
8. Thrombocytopenia, defined as Platelet count $< 150,000/\text{mm}^3$ Patients can be transfused to meet eligibility criteria
9. Severe chest wall deformity, which would preclude placement of the PV conduit
10. Known hypersensitivity to anticoagulants and antiplatelet drugs and to the device materials
11. Immunocompromised patient defined as: autoimmune disease, patients receiving immunosuppressant drugs or immune stimulant drugs
12. Patient has chronic inflammatory / autoimmune disease
13. Need for emergency cardiac or vascular surgery or intervention
14. Major or progressive non-cardiac disease (liver failure, renal failure, cancer) that has a life expectancy of less than one year
15. Currently participating, or participated within the last 30 days, in an investigational drug or device study
16. Alcohol or drug abuse as defined by DSM IV-TR criteria for substance abuse - this includes the illicit use of cannabis within the last 12 months
17. Patient has medical, social or psychosocial factors that, in the opinion of the Investigator, could have impact on safety or compliance

Conditions & Interventions

Interventions:

DEVICE: Surgical Right Ventricular Outflow Tract Reconstruction

Conditions:

Tetralogy of Fallot, Pulmonary Stenosis, Truncus Arteriosus, Transposition of Great Vessels, Pulmonary Atresia, Ross Procedure

Keywords:

Right Ventricular Outflow Tract Reconstruction, Pulmonary Valve, MASA Valve, Pulmonary Valve Replacement

More Information

Description:

The MASA Valve Early Feasibility Study (MVEFS) multi-site interventional clinical trial within the United States of America with each center following a common protocol. The objective of the trial is to evaluate the safety and probable benefit of MASA Valve in the indicated subset of patients requiring Right Ventricular Outflow Tract Reconstruction (RVOTR). As an early feasibility study, the purpose is to determine the feasibility of success of the device in order to gather early data towards a future pivotal study and/or regulatory clearance submission.

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Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT05452720

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