

MASA Valve Early Feasibility Study

NCT05452720

Status	RECRUITING
Phase	Not Applicable
Sponsor	PECA Labs
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (5)

- At least one of the following: Right Ventricular to Pulmonary Artery mean gradient ≥ 35 mm Hg, moderate or severe Pulmonary regurgitation (e3+), or clinical indication for replacement of their native or prosthetic pulmonary valve with a prosthesis.
- Age ≤ 22 years
- Patient is geographically stable and willing to return for 1 year follow-up for the trial.
- Patient's legal guardian should be willing to provide informed consent (IC) at the hospital location where they are being enrolled.
- 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 (17)

- Patient is in need of or has presence of a prosthetic heart valve at any other position
- Patient has a need for concomitant surgical procedures (non-cardiac)
- Patients with previously implanted pacemaker (including defibrillators) or mechanical valves
- 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)
- Patient has an active endocarditis

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

Locations (5 total)

OSF Childrens Hospital of Illinois, Peoria, Illinois, United States
Boston Childrens Hospital, Boston, Massachusetts, United States
Cincinnati Children's Hospital, Cincinnati, Ohio, United States
... and 2 more locations