Starlight Cardiovascular Lifeline Ductus Arteriosus Stent IDE Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 minute to 6 months old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Parental or legal authorized representative provide consent for study enrollment
2. Infants < 6 months of age
3. Diagnosis of congenital heart defect with ductal-dependent pulmonary circulation requiring infusion of prostaglandins
4. Requires ductus arteriosus stent diameters of 3.5mm or 4mm and stent lengths between 16mm and 28mm

Exclusion Criteria:

1. Active blood stream infection
2. Active or history of endocarditis
3. Body weight <2.5kg
4. Gestational age <32 weeks at birth
5. Complete heart block
6. Total Anomalous Pulmonary Venous Return
7. Anatomic variation judged to be inappropriate for ductal stenting per the treating interventionalist
8. Presence of an aortopulmonary collateral that is expected to require unifocalization
9. Non-confluent pulmonary arteries (i.e. isolated pulmonary artery of ductal origin) or bilateral patent ductus arteriosus (PDA)
10. Pulmonary atresia with intact ventricular septum with RV-dependent coronary circulation
11. Currently participating in an investigational drug study or another device study that would confound the study results
12. Patient who is on extracorporeal membrane oxygenation (ECMO), ventricular assist device (VAD), or dialysis prior to ductal stenting procedure
13. Major co-morbidities which, in the opinion of the investigator, would negatively alter expected 1-year survival (e.g., intracranial hemorrhage, renal failure, etc.)
14. Patient who is undergoing another transcatheter procedure (e.g., atrial septostomy, aortic arch intervention, or right ventricular outflow tract intervention) during or within 24 hours prior to the ductus arteriosus stenting procedure
15. Patient who, at the time of enrollment, is deemed not to be a candidate for eventual stage II palliation of single ventricle heart disease, complete surgical repair, nor transcatheter treatment with resultant biventricular circulation
16. Patient who does not plan to return to the enrolling center or another participating center for stage II palliation, complete surgical repair, or definitive catheterization procedure
17. Contraindications to peri-procedural anticoagulation
18. Known to be non-responsive to aspirin or other antiplatelet therapies
19. Known hypersensitivity or allergy to Nickel
20. Known hypersensitivity to contrast media that cannot be adequately pre-medicated

Conditions & Interventions

Interventions:
DEVICE: Ductus Arteriosus Stent
Conditions:
Congenital Heart Disease, Congenital Heart Disease (CHD)
Keywords:
Ductus Arteriosus Stent, pediatric stent, Lifeline Stent

More Information

Description:
Starlight Cardiovascular, Inc. is sponsoring a prospective, multi-center, study to evaluate safety and effectiveness of the Lifeline Ductus Arteriosus Stent System. The study device is a stent that is designed to maintain patency of the Ductus Arteriosus for children who need blood flow through that part of the heart.

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clinicalstudies@cchmc.org if you have questions or need assistance.