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SVR Study Basics

SVR is a Trial of Right Ventricular vs. Modified Blalock-Taussig Shunt in Infants with Single Ventricle Defect Undergoing Staged Reconstruction. Its short title is Single Ventricle Reconstruction (SVR). The target number is 466 babies. The accrual period is 33 months.

Study Design

A Phase III, randomized trial of the RV-to-PA shunt vs. MBTS of patients undergoing a *Norwood procedure*. Pre- and post-operative data, neurodevelopment and genetic evaluation information is collected and patients are followed until 14 months of age.

Primary Endpoint

Death or cardiac transplantation at 12 months of age

Secondary Endpoints

1. Post-operative morbidity following the Norwood procedure
2. Post-operative morbidity following Stage II palliation
3. Unintended cardiovascular interventional procedures in the first 12 months of life
4. RV function and pulmonary artery growth at Stage II palliation
5. Neurodevelopmental status at 14 months of age

Inclusion Criteria

1. Diagnosis of hypoplastic left heart syndrome or related single, morphologic right ventricle anomaly
2. Planned Norwood procedure
3. Informed consent of parent or legal guardian

Exclusion Criteria

1. Single, morphologic left ventricle anomaly
2. Pre-operative identification of anatomy rendering a MBTS or RV-to-PA shunt technically impossible
3. Any major congenital anomaly or acquired extra-cardiac disorder that could independently affect the likelihood of the subject meeting the primary endpoint

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