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ISV Study Basics

ISV is a Trial of ACE Inhibition in Infants with Single Ventricle. The short title for the study is Infant Single Ventricle (ISV). The target number of participants is 230. The accrual period is 43 months and it began 08/25/2005

Study Design

A Phase III, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of administering ACE-I to infants with single ventricle physiology. Data is collected to determine the effect of ACE inhibition on ventricular function and remodeling and patients are followed until 14 months of age.

Primary Endpoint

Weight-for-age Z-score at 14 months of age

Secondary Endpoints

1. Ross Heart Failure Class
2. Neurohormonal activation (BNP level)
3. Neurodevelopmental and functional status
4. Ventricular geometry, function and AV valve regurgitation
5. Incidence of adverse events

Inclusion Criteria

1. Single ventricle physiology
2. ≤ 45 days of age
3. Planned Glenn shunt procedure

Exclusion Criteria

1. Birth weight < 2.5 kg (38+ weeks gestation)
2. Birth weight < 10 th percentile (35-37 weeks gestation)
3. < 35 weeks gestation
4. Pulmonary atresia with intact ventricular septum
5. < 3 days after palliative surgical procedure
6. Aortic oxygen saturation $< 65\%$
7. Current mechanical ventilation or IV inotropic support
8. Creatinine > 1.0 mg/dL
9. ANC < 1000 cells/mL
10. Chromosomal or phenotypic syndromes of non-cardiac abnormalities associated with growth failure
11. Prior ACE-I use for > 7 consecutive days

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