Milrinone for Prevention of Post-ligation Cardiac Syndrome Trial

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Up to 3 month(s) old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Gestational age at birth ≤27 weeks (and 6 days) and postnatal age < 3 months at intervention
- Invasive or non-invasive positive pressure respiratory support (does not include low flow nasal cannula)
- Hemodynamically significant PDA with minimum transductal diameter ≥1.0 mm within 2 days of intervention
- Decision by clinical team to proceed with PDA closure via surgical ligation or percutaneous cardiac catheterization based on clinical and echocardiography features of hemodynamic significance.

Exclusion Criteria:

- Any major congenital malformation
- Congenital heart disease (except small (≤1mm) muscular ventricular septal defects, or small/moderate (<3mm) atrial septal defect)
- Acute renal failure defined by urine output < 0.5 mL/kg/hour OR rise of serum creatinine by 0.3 mg/dL within 48 hours OR rise of serum creatinine more than 40% above baseline serum creatinine within prior 72 hours.
- Systemic administration of vasodilator/inodilator agents
- Prior history of arrhythmia

Conditions & Interventions

Interventions:
DRUG: Milrinone infusion, DRUG: Placebo infusion
Conditions:
Post-ligation Cardiac Syndrome

More Information

Description:
The goal of this Phase 3, randomized, masked clinical trial is to is to find out whether milrinone, when given to infants after PDA closure, will help the heart work better by supplying oxygen to the lungs and tissues. The main questions it aims to answer are: 1. to determine if milrinone decreases the risk of death or PLCS within 7 days of the procedure, compared to standard treatment; and 2. to determine the effects of milrinone on two-year survival and neurodevelopmental outcome.

Contact(s): Traci Beiersdorfer - Traci.Beiersdorfer@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT06679855