Biomarker and Renal Angina Validation to Assess Heart-Kidney Outcomes After Amino Acid Therapy

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Up to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Expected to be at high risk of developing acute kidney injury after cardiac surgery based on Age, The Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STAT) score, and anticipated cardiopulmonary bypass time
- Age less than or equal to 18 years
- Weight greater than or equal to 5 kilograms

Exclusion Criteria:

- Preoperative extracorporeal organ support
- History of chronic kidney disease
- Known or suspected inborn errors of amino acid metabolism
- Known hypersensitivity to amino acids
- Aspartate Aminotransferase (AST) or Alanine Aminotransferase (ALT) > 3 times the upper limit of normal for age/gender
- Preterm infants less than 6 months of age who were born at less than 36 weeks gestational age
- Anuria at the time of randomization
- Expected use of total parental nutrition (TPN) within the first 72 hours post-operatively

Conditions & Interventions

Interventions:
DRUG: Amino Acid infusion, DRUG: Lactated ringers solution
Conditions:
Acute Kidney Injury, Mechanical Ventilation
Keywords:
Cardiac Bypass, Pediatric, Acute Kidney Injury, Amino Acids

More Information

Description:
The goal of the BRAVE-HEART study is to learn if an amino acid infusion can reduce the risk of developing acute kidney injury after cardiac surgery ir children. The main questions it aims to answer are: 1. Does an amino acid infusion decrease the number of participants with acute kidney injury? 2. Does an amino acid infusion decrease the number of days that participants are on a ventilator after cardiac surgery? Researchers will compare amino acids to a placebo (a look-alike substance that contains no drug) to see if amino acids decrease the number of participants with acute kidney injury. Participants will receive an amino acid or placebo infusion for up to 72 hours starting during cardiac surgery and only while in the operating room or the intensive care unit.

Contact(s): Kelli Krallman, RN, BSN, MS - kelli.krallman@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT07212595