

NO During CPB in Neonates to Reduce Risk of AKI

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 1 day to 31 days old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- All neonates (≤ 31 days) undergoing cardiac surgery with CPB for CHD will be deemed eligible for enrollment.

Exclusion Criteria:

1. Failure to obtain informed consent from parent/guardian
2. Clinical signs of preoperative persistent elevated pulmonary vascular resistance,
3. Emergency surgery,
4. Episode of cardiac arrest within 1 week before surgery,
5. Recent treatment with steroids and/or a condition that may require treatment with steroids (excluding steroid administration specifically for CPB),
6. Use of inhaled NO (iNO) immediately prior to surgery,
7. Structural renal abnormalities by ultrasound,
8. Preoperative AKI,
9. Use of other investigational drugs,
10. Weight less than < 2 kg,
11. Gestational age < 36 weeks,
12. Major extracardiac congenital anomalies,
13. Non-English speakers.

Conditions & Interventions

Interventions:

DRUG: Nitric Oxide, DRUG: Oxygen

Conditions:

AKI, CHD - Congenital Heart Disease, Surgery

More Information

Description:

Acute kidney injury (AKI) following cardiac surgery for congenital heart defects (CHD) in children affects up to 60% of high risk-patients and is a major cause of both short- and long-term morbidity and mortality. Despite effort, to date, no successful therapeutic agent has gained widespread success in preventing this postoperative decline in renal function. Nitric oxide is an intricate regulator of acute inflammation and coagulation and is a potent vasodilator. The investigators hypothesize that nitric oxide, administered during cardiopulmonary bypass (CPB), may reduce the incidence of AKI.

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Principal Investigator ID:

Phase: PHASE3

IRB Number:

System ID: NCT04216927

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