Evaluation of Analgesia for Cardiac Elective Surgery in Children

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Children aged 3-years - <18 years
- ASA physical status 1, 2, or 3
- Participant or legal guardian can speak and read English or Spanish
- Undergoing the following cardiac surgeries (Categories 1 & 2) that are associated with significant acute surgical pain

STS Category 1:

- ASD, PFO closure
- VSD repairs,
- Aortic stenosis sub-valvular repair
- ASD and Partial anomalous venous return repair
- AV canal transitional
- Conduit replacement
- Valve replacement (AVR, PVR)
- TOF repair without ventriculostomy

STS Category 2:

- Glenn shunt (on Bypass only)
- Fontan surgery (on Bypass only)
- Pulmonary artery plasty (main)
- Left Atrium (LA) to Pulmonary Artery (PA) conduit replacement.

Exclusion Criteria:

- Pregnant patients
- Methadone allergy
- Preoperative prolonged QTc more than 460 msec (-30 days to 0 day)
- Subjects undergoing concomitant treatment with known cytochrome P450 inhibitors included in methadone labeling (i.e. macrolides (e.g. erythromycin), azole-antifungal agents (e.g. ketoconazole, voriconazole), protease inhibitors (e.g. ritonavir), fluconazole, SSRIs (e.g. sertraline, fluvoxamine)
- Preoperative opioid use within 30 days before surgery
- History of severe sleep apnea (have a sleep study with an AHI index score more than 10 or clinical signs of sleep disordered breathing - snoring, daytime drowsiness)
- Significant liver, kidney, neurological disease, developmental delay, or any other co-existing medical condition per discretion of the clinical investigator

Conditions & Interventions

Interventions:
DRUG: Methadone based ERAS, DRUG: Non-methadone based group
Conditions:
Pediatric Cardiac Surgery

More Information

Description:
The purpose of this study is to look at a standardized methadone-based enhanced recovery after surgery protocol following pediatric cardiac surgery. This study will consist of randomly assigning children to receive the methadone-based recovery procedures or to receive current standard of care recovery procedures. Randomly assigning means that there is a 50/50 chance, like a coin flip, of being assigned to either research group.

Contact(s): Isabelle Allen - isabelle.allen@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT06626035

clinicalstudies@cchmc.org if you have questions or need assistance.