

Evaluation of Analgesia for Spine Fusion Elective Surgery in Children

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 10 years to 18 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Age 10 - < 18 years
2. American Society of Anesthesiologists (ASA) Physical Status 1 or 2
3. Undergoing PSF for idiopathic scoliosis
4. Participant or legal guardian can speak and read English or Spanish

Exclusion Criteria:

1. Pregnant patients
2. Methadone allergy
3. Preoperative prolonged QTc more than 460 msec (-30 days to 0 day)
4. 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)
5. Preoperative opioid use within 30 days before surgery
6. History of severe sleep apnea, defined as a prior sleep study demonstrating an apnea-hypopnea index (AHI) greater than 10.
7. 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:

Idiopathic Scoliosis

More Information

Description:

The multicenter PRECISE Analgesia (Prospective Randomized Evaluation of Analgesia for Idiopathic Scoliosis Spine Fusion Elective Surgery in Children) trials will a) implement and investigate the efficacy and safety of multidose methadone-based standardized enhanced recovery after surgery (ERAS) protocol, and b) develop personalized ERAS protocols including precision methadone and oxycodone dosing and c) personalized analgesia for the safe and effective opioid-sparing management of surgical pain after posterior spine fusion (PSF) in children.

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE3

IRB Number:

System ID: NCT06626503

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