Comparing Analgesic Regimen Effectiveness and Safety for Surgery for Kids Trial

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years to 20 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- No significant analgesic medication use before surgery as defined in the protocol. For this study, we define significant analgesic medication use before surgery as prescriptions reported by the child or caregiver for 6 days or more of opioid medications in the past 90 days (aligning with American Pediatric Guidelines that were published in September 2024 after the project was funded), excepting surgical team prescriptions within the week of surgery.
- Undergo one the following: tonsil removal (with or without adenoid removal), gallbladder removal (laparoscopic), and knee scope (arthroscopy).

Exclusion Criteria:

- Anticipated other surgery within 12 months
- Anticipated life expectancy of <12 months
- Those that have legal guardians (due to special permission to enroll in trials)
- Participants with complex chronic conditions per the Pediatric Medical Complexity Algorithm (e.g., trisomy 21)
- Patients with contraindications to non-steroidal anti-inflammatory drug (NSAID) drugs in the NSAID arm, opioid drugs in the opioid arm, or acetaminophen will be excluded.
- Liver disease
- Acute psychiatric instability (defined as current uncontrolled severe depression, severe post-traumatic stress disorder (PTSD), or suicidal ideation), substance use disorder not in remission or treatment, and history of diversion of controlled substances (opioids)

Conditions & Interventions

Interventions:
DRUG: NSAID, DRUG: Opioid, DRUG: Acetaminophen, DRUG: Ibuprofen
Conditions:
Surgery, Pain, Post Operative
Keywords:
Medications after surgery, NSAIDS, Acetaminophen, Opioids, Analgesics, non-narcotic, Tonsil removal, Gallbladder removal, Knee scope, Analgesics, opioid

More Information

Description:
This trial is being completed to compare two commonly used options to treat pain after discharge from surgery. Participants that undergo tonsil removal, gallbladder removal, and knee scope will be eligible to enroll. Eligible participants will be randomized to prescription of 1 of 2 groups of medications (Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) plus acetaminophen or low dose opioids with the NSAIDs plus acetaminophen. The key question the study seeks to answer is which option will have the best outcomes and with the fewest side effects?

Contact(s): Knox Jennifer - jennifer.knox@cchmc.org
Phase: PHASE4
System ID: NCT06671002

Thank you for choosing StudyFinder. Please visit http://studyfinder.cchmc.org to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.