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CC-CHOC Pediatric Point Person Project (P4)

Protocol Information Form

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Submitted April 20, 2012

Participant ID #6 Codeine

Sponsor CRO

Study Title A Multicenter, Open-Label, Safety and Pharmacokinetic Study of Oral Codeine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Post-procedural Pain

Target Population Children ages 2-17 (inclusive) with mild to moderate post-procedural pain (e.g. procedures such as inguinal/umbilical hernia repair, tonsillectomy, adenoidectomy, tympanostomy tubes, laparoscopic procedures, orthopedic procedures). (Define a patient that could be enrolled in this study)

Study Objectives Regulatory obligation. Safety and tolerability, PK, proportion of patients receiving more than one dose.

Key Inclusion/Exclusion Criteria

Inclusion: Ages 2-17 (inclusive) Routine pediatric procedure that is expected to cause at least mild to moderate pain, and treated with at least 1 dose of oral codeine
Exclusion: Chronic opioid use (e.g. >7 days usage within 30 days before procedure). Impaired liver function or active/chronic liver disease. Impaired renal function or disease.

Short Overview of Study Design Open label safety and PK study. Up to 14 day prescreening period (can screen same day as surgical procedure). Up to 24 hours of dosing for mild to moderate pain.

Study Synopsis

Total Number of Patients to be Enrolled 75 receiving at least 1 dose, of which at least 50 receiving multiple doses. 35 sites are required.

Enrollment Period June 2012 through June 2013

Miscellaneous Details/Requirements

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Any questions? Email ctsa_childhealth@ctsaC4.org