DCRI
PEDIATRIC STUDIES RECRUITMENT

Duke Clinical Research Institute

The Duke Clinical Research Institute, together with its esteemed site community partners, is addressing clinical research challenges that will shape the future of medical care for years to come. Our investigators and study coordinators are true collaborators in fulfilling our mission— ***to develop, share, and implement knowledge that improves health around the world through innovative clinical research.***

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PHARMACOKINETICS AND SAFETY OF ANESTHETICS AND ANALGESICS IN CHILDREN AND ADOLESCENTS (ANA01)

What is ANA01?

Anesthetics and analgesics are commonly used off-label in children despite inadequate information on drug efficacy, safety, and dosing in this population. This study hopes to fill the knowledge gap and inform drug labeling for the use of these drugs in children.

ClinicalTrials.gov Identifier: NCT03427736

Currently Recruiting

Participants

Study Design

ANA01 is a pragmatic, multi-drug protocol of anesthetics and analgesics. Drugs are administered per routine medical care for indications labeled in adults.

Patient Population

Currently enrolling 60 children per drug group, and 42 caregivers of young children in acute pain. Drugs of interest may include: hydromorphone, ketorolac, ketamine, oxycodone, and morphine.

Study Objectives

Primary:

- Characterize the pharmacokinetics of anesthetics and analgesics

Exploratory:

- Characterize the safety of anesthetics and analgesics
- Characterize events of special interest associated with anesthetics and analgesics
- Identify the impact of pharmacogenomics on the pharmacokinetics of selected anesthetics and analgesics

Duration of Study Participation

Participants may have biological specimens and data collection for up to 4 days after they were administered the drug (up to 5 blood sample collections). Parents may complete follow up questionnaires up to 12 months after drug administration and/or at discharge.

Study Centers

~15 sites in the United States and Canada

Study Timeline

Enrollment began the fourth quarter of 2017 and is ongoing.

Sponsor

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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PHARMACOKINETICS AND SAFETY OF COMMONLY USED DRUGS IN LACTATING WOMEN AND BREASTFED INFANTS (BMS01)

What is BMS01?

BMS01 will study mothers and their breastfeeding babies to track how different drugs of interest (DOI) are passed through breastmilk to determine dosing levels that are safe for mom and baby. The study will characterize the pharmacokinetics and safety profile of understudied drugs administered per standard of care to lactating women and thus their breastfed infants as prescribed by their healthcare provider.

ClinicalTrials.gov Identifier: NCT03511118

Currently Recruiting

Sites and participants

Study Design

Multicenter, opportunistic study for breastfeeding moms who are on drugs of interest (DOI) and their infants. The medications are given to the moms through their primary provider as standard of care (SOC) drugs.

Study Objectives

Primary Endpoint:

- PK of selected DOIs in lactating women and breastfed infants

Secondary Endpoint:

- Drug-specific safety outcomes of commonly used drugs in infants exposed to drugs in breast milk

Ten DOIs have completed enrollment: tranexamic acid, labetalol, metformin, nifedipine, clindamycin, oxycodone, azithromycin, escitalopram, sertraline, and ondansetron. Nine additional DOIs are currently open to enrollment: methylphenidate, sumatriptan, cyclobenzaprine, gabapentin, trazodone, venlafaxine, citalopram, furosemide,
and topiramate.

Duration of Study Participation

Approximately 50 eligible lactating women and their breastfed infants per DOI will be enrolled for one or more DOIs with a single consent. Mothers and infants are expected to remain in the study until the infants reach 180 days of age. Participants who consent to participate in the safety and long-term follow up study may continue to provide safety data and long-term outcome data for up to infant age 24 months (+/- 3 months).

Study Centers

20 sites across the United States and Canada

Study Timeline

Enrollment began September 2018 and is ongoing.

Sponsors

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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PHARMACOKINETICS AND SAFETY PROFILE OF DIGOXIN IN INFANTS WITH SINGLE VENTRICLE CONGENITAL HEART DISEASE (DGX01)

What is DGX01?

Phase I, prospective, multi-center, open-label, PK and safety profile study of dixogin during the interstage (between S1P and S2P surgeries) period in children with single ventricle congenital heart disease.

ClinicalTrials.gov ID NCT03877965

Currently Recruiting

Sites

Study Drug

Digoxin

Treatment/Intervention

Standard of care treatment

Patient Population

The patient population will include up to 48 participants under six-months of age at enrollment who have been diagnosed with single ventricle congenital heart disease and are post-S1P and pre-S2p, being treated with enteral digoxin.

Study Objectives

Primary endpoint: Characterize the pharmacokinetics of enteral digoxin in infants with single ventricle congenital heart disease.
Secondary endpoint: Determine the safety profile of enteral digoxin in infants with single ventricle congenital heart disease.
Exploratory endpoint: Obtain preliminary efficacy data for enteral digoxin in infants with single ventricle congenital heart disease.

Duration of Study Participation

Study participation duration is approximately 196 (± 14) days. Follow-up occurs up to six months.

Study Timeline

March 2019 to September 2022

Study Centers

13 clinical sites within the United States

Sample Size

Up to 48 infants

Sponsor/Funding Support

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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LONG-TERM ANTIPSYCHOTIC PEDIATRIC SAFETY TRIAL (LAP01)

What is LAP01?

Phase IV trial collecting longitudinal post-marketing safety data, neuromotor adverse effects, and developmental and quality of life outcomes over a 2-year period to assess the impact of multiyear treatment with antipsychotics.

An optional registry sub-study will allow follow-up of existing participants for an additional 3-years.

ClinicalTrials.gov Identifier: NCT03522168

Currently Recruiting

Sites and participants (through July 31, 2021)

Study Design

Prospective, multisite, observational study to collect robust longitudinal post-marketing safety data from multiyear pediatric treatment with risperidone or aripiprazole.

Participant Population

350 children ages 3 to <18 years old per drug group (Risperidone and Aripiprazole), at least 30 percent of children in each group with <3 months prior treatment with any antipsychotic.

Study Objectives

Primary Endpoint:

- Pathologic weight change per longitudinal change in BMI z-score from study start

Secondary Endpoints:

- Safety outcomes of special interest
- Potential long-term benefits
- Pharmacokinetics in children ages 6 to <10 years old and obese children 6 to <18 years old

Duration of Study Participation

In-person visits occur every 6 months with web, phone, and (remote) mail visits every month between in-person visits until July 31, 2021. Participants will have the option to continue in a registry sub-study, which will include annual in-person visits. Remote height, weight, and survey tasks will be collected via a mobile app between in-person visits.

Study Centers

~60 sites

Study Timelines

Enrollment began the first quarter of 2018 and is ongoing through July 31, 2021.

Sponsor

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PHARMACOKINETICS, PHARMACODYNAMICS, AND SAFETY PROFILE OF UNDERSTUDIED DRUGS ADMINISTERED TO CHILDREN PER STANDARD OF CARE (POP02 AND POP02-COVID SUB-STUDY)

What are POP02 and POP02-COVID Sub-Study?

The goal of POP02 is to characterize the pharmacokinetics of understudied drugs for which specific dosing recommendations and safety data are lacking. By taking advantage of procedures done as part of routine medical care (for example, blood draws), this study will provide better understanding of drug exposure in children. POP02 will help provide valuable information for therapeutics used in special populations, such as critically ill children receiving ECMO or CRRT, premature infants, children with Down syndrome, children with obesity, and children affected by acute COVID-19 or multisystem inflammatory syndrome in children (MIS-C).

POP02-COVID Sub-Study: At the onset of the COVID-19 pandemic, POP02 expanded to include a sub-study that collects real-time COVID-19 related data in children affected by acute COVID-19 and MIS-C. POP02-COVID is also evaluating several therapeutics to potentially treat COVID-19 patients age 0 to <21 years old.

ClinicalTrials.gov Identifier: NCT04278404

Currently Recruiting

Sites and participants

Study Drug

Multiple drugs of interest administered to children per standard of care.

Patient Population

Children under 21 years of age

Study Objectives

The primary objective of this study is to evaluate the pharmacokinetics of understudied drugs currently being administered to children per standard of care as prescribed by their treating provider.

The exploratory objectives include:

1. Explore the pharmacodynamics of understudied drugs currently being administered to children;
2. Evaluate the influence of genetic factors and metabolic and protein profiles on therapeutic exposure;
3. Evaluate safety profile of understudied drugs;
4. Describe combinations of therapies used to treat children affected by acute COVID-19 or MIS-C; and
5. Evaluate factors, including whole genome sequencing, that influence susceptibility, severity, and outcomes of children affected by acute COVID-19 or MIS-C.

Duration of Study Participation

90 days (210 days for participants with Down syndrome)

Study Timeline

Up to 4 years

Study Centers

Approximately 60 sites selected with 100 total sites planned.

Sample Size

Up to 5,000 participants

Sponsor/Funding Support

National Institute of Child Health and Human Development (NICHD)

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SILDENAFIL (SIL02)

SILDENAFIL (SIL02)

Safety of Sildenafil in Premature Infants at Risk of Bronchopulmonary Dysplasia (BPD)

What is SIL02?

Infants at less than 29 weeks gestational age will be randomized in a dose escalating approach 3:1 (sildenafil: placebo) sequentially, into one of three cohorts (nasal continuous airway pressure, nasal intermittent positive pressure ventilation, or nasal cannula flow > 1LPM) or mechanical ventilation (high frequency or conventional). Information about hospitalization will be collected at 36 weeks post-menstrual age and/or at discharge.

ClinicalTrials.gov Identifier: NCT03142568

Currently Recruiting

Participants

Study Design

Multicenter, randomized, placebo-controlled, dose escalating, double masked, safety study

Patient Population

120 infants < 29 weeks gestational age at birth

Study Objectives

Primary Endpoint:

- Description of the safety of sildenafil in premature infants at risk of BPD

Secondary Endpoint:

- Preliminary effectiveness-reduction in risk of bronchopulmonary dysplasia
- Pharmacokinetics (PK) of sildenafil
- Change in risk of bronchopulmonary dysplasia

Duration of Study Participation

Study participation is up to 42 days (28 days of study drug plus 14 days of safety follow-up).

Study Centers

~30 sites in the United States and Canada

Study Timelines

Enrollment began April 2018 and is ongoing.

Sponsors

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

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