Pharmacokinetics, Pharmacodynamics, and Safety Profile of Understudied Drugs Administered to Children Per Standard of Care (POPS)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: up to 20 Years old
Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:
1. Participant is < 21 years of age and
2. is receiving understudied drugs of interest (DOIs) per standard of care (SOC) as prescribed by their treating provider OR
2. is NOT receiving one or more of the study drugs of interest but is SARS-CoV-2 positive within 60 days prior to enrollment. Parent/ Legal Guardian/ Adult Participant can understand the consent process and is willing to provide informed consent/ HIPAA

Exclusion Criteria:
1. Participant has a known pregnancy
2. Has had intermittent dialysis within previous 24 hours
3. Has had a kidney transplant within previous 30 days
4. Has had a liver transplant within previous 1 year
5. Has had a stem cell transplant within previous 1 year
6. Has had a hematopoietic stem cell transplant within previous 1 year
7. Has had a stem cell transplant within previous 1 year
8. Has had plasmapheresis within the previous 24 hours
9. Has a Ventricular Assist Device
10. Has any condition which would make the participant, in the opinion of the investigator, unsuitable for the study

Conditions & Interventions

Interventions:
Drug: The POP02 study is collecting bodily fluid samples (i.e., whole blood, effluent samples) of children prescribed the following drugs of interest per standard of care:

Conditions:
Coronavirus Infection (COVID-19), Pulmonary Arterial Hypertension, Urinary Tract Infections in Children, Hypertension, Pain, Hyperphosphatemia, Primary Hyperaldosteronism, Edema, Hypokalemia, Heart Failure, Hemophilia, Menorrhagia, Insomnia, Pneumonia, Skin Infection, Arrhythmia, Asthma in Children, Bronchopulmonary Dysplasia, Adrenal Insufficiency, Fibrinolysis, Hemorrhage, Attention Deficit Hyperactivity Disorder, Multisystem Inflammatory Syndrome in Children (MIS-C), Kawasaki Disease, Coagulation Disorder, Down Syndrome

More Information

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Phase:
IRB Number:
System ID: NCT04278404

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