Pharmacokinetic Study of Venetoclax Tablets Crushed and Dissolved Into a Solution

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 0 years to 38 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age: Patients must be <39 years of age at time of study enrollment
- Diagnosis: Patients may have a diagnosis of any hematologic malignancy
- Central access: Patients must have an existing venous or arterial access line for PK blood draws
- Weight requirement: Patients must weigh at least 5.5 kg at the time of enrollment
- Venetoclax: Patients must be receiving any dose of venetoclax given as a solution made from crushed tablets by mouth (PO) or via nasogastric (NG), or G-tube as prescribed by their treating oncologist.
- Concurrent chemotherapy medications: Patients may receive venetoclax as a single agent or in combination with any other chemotherapeutic agents.

Exclusion Criteria:

- Pregnant women are excluded from this study because venetoclax has the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with venetoclax, breastfeeding should be discontinued if the mother is treated with venetoclax.
- Males or females of reproductive potential may not participate unless they have agreed to use an effective contraceptive method while on study treatment and for six months following completion.

Conditions & Interventions

Interventions:
OTHER: 1. Drug: The Venetoclax PK study is collecting bodily fluid samples (ie., whole blood and optional cerebrospinal fluid) of patients prescribed venetoclax as crushed tablets per standard of care.
Conditions:
Hematologic Malignancy, Leukemia, Lymphoma, Acute Lymphocytic Leukemia, ALL, Acute Myelogenous Leukemia, AML, Chronic Myelogenous Leukemia, CML, Myeloproliferative Neoplasm, Non Hodgkin Lymphoma, Hodgkin Lymphoma, Diffuse Large B Cell Lymphoma, Follicular Lymphoma, Burkitt Lymphoma, T-cell Lymphoma, B Cell Lymphoma, Peripheral T Cell Lymphoma, Cutaneous B-Cell Lymphoma
Keywords:
Venetoclax, Pediatric AML, Pediatric Relapsed/Refractory AML

More Information

Description:
The use of venetoclax-based therapies for pediatric patients with relapsed or refractory malignancies is increasingly common outside of the clinical trial setting. For patients who cannot swallow tablets, it is common to crush the tablets and dissolve them in liquid to create a solution. However, no PK data exists in adults or children using crushed tablets dissolved in liquid in this manner, and as a result, the venetoclax exposure with this solution is unknown. Primary Objectives • To determine the pharmacokinetics of venetoclax when commercially available tablets are crushed and dissolved into a solution Secondary Objectives * To evaluate the safety of crushed venetoclax tablets administered as an oral solution * To determine the pharmacokinetics of venetoclax solution in patients receiving concomitant strong and moderate CYP3A inhibitors * To determine potential pharmacokinetic differences based on route of venetoclax solution administration (ie. PO vs NG tube vs G-tube) * To determine the concentration of venetoclax in cerebral spinal fluid when administered as an oral solution

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