Testing the Addition of the Anti-cancer Drug Venetoclax and/or the Anti-cancer Immunotherapy Blinatumomab to the Usual Chemotherapy Treatment for Infants With Newly Diagnosed KMT2A-rearranged or KMT2A-non-rearranged Leukemia

Status: RECRUITING

Eligibility Criteria

Age: Up to 1 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* All patients must be enrolled on APEC14B1 and consented to eligibility screening (part A) prior to treatment and enrollment on AALL2321 * Infants (aged 365 days or less) on the date of diagnosis are eligible; infants must be \> 36 weeks gestational age at the time of enrollment * Patients must have newly diagnosed B-acute lymphoblastic leukemia (B-ALL, 2017 World Health Organization \[WHO\] classification), also termed B-precursor ALL, or acute leukemia of ambiguous lineage (ALAL), which includes mixed phenotype acute leukemia. For patients with ALAL, the immunophenotype of the leukemia must comprise at least 50% B lineage * Diagnostic immunophenotype: Leukemia cells must express CD19

Exclusion Criteria:

* Patients with Down Syndrome * Patients with secondary B-ALL that developed after treatment of a prior malignancy with cytotoxic chemotherapy * Patients must not have received any cytotoxic chemotherapy for either the current diagnosis of infant ALL or for any cancer diagnosis prior to the initiation of protocol therapy, with the exception of: * Steroid pretreatment: * PredniSONE, prednisoLONE, or methylPREDNISolone for ≤ 72 hours (3 days) in the 7 days prior to enrollment. The dose of predniSONE, prednisoLONE or methylPREDNISolone does not affect eligibility * Inhaled and topical steroids are not considered pretreatment * Note: Pretreatment with dexamethasone in the 28 days prior to initiation of protocol therapy is not allowed with the exception of a single dose of dexamethasone used during or within 6 hours prior to or after sedation to prevent or treat airway edema. However, prior exposure to ANY steroids that occurred \> 28 days before enrollment does not affect eligibility * Intrathecal cytarabine or methotrexate: * An intrathecal dose of cytarabine or methotrexate in the 7 days prior to enrollment does not affect eligibility * Note: The preference is to defer the diagnostic lumbar puncture with intrathecal chemotherapy to day 1 of induction to allow for cytoreduction of circulating blasts and decrease the potential for central nervous system (CNS) contamination due to a traumatic tap. If done prior to day 1 of induction, these results will be used to determine CNS status * Hydroxyurea: * Pretreatment with ≤ 72 hours (3 days) of hydroxyurea in the 7 days prior to enrollment does not affect eligibility * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA) and National Cancer Institute (NCI) requirements for human studies must be met

Conditions & Interventions

Interventions:
DRUG: Asparaginase Erwinia chrysanthemi, PROCEDURE: Biospecimen Collection, BIOLOGICAL: Blinatumomab, PROCEDURE: Bone Marrow Aspiration, DRUG: Calaspargase Pegol, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, DRUG: Cytarabine, DRUG: Daunorubicin, DRUG: Dexamethasone, DRUG: Doxorubicin, PROCEDURE: Echocardiography Test, PROCEDURE: FDG-Positron Emission Tomography, DRUG: Leucovorin, DRUG: Levoleucovorin, PROCEDURE: Lumbar Puncture, PROCEDURE: Magnetic Resonance Imaging, DRUG: Mercaptopurine, DRUG: Methotrexate, DRUG: Methylprednisolone, PROCEDURE: Multigated Acquisition Scan, DRUG: Prednisolone, DRUG: Prednisone, DRUG: Therapeutic Hydrocortisone, DRUG: Thioguanine, DRUG: Venetoclax, DRUG: Vincristine
Conditions:
Acute Leukemia of Ambiguous Lineage, B Acute Lymphoblastic Leukemia

More Information

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