AALL2321; A Phase 2 Study of Blinatumomab in Combination with Chemotherapy for Infants with Newly Diagnosed Acute Lymphoblastic Leukemia with Randomization of KMT2A-Rearranged Patients to Addition of Venetoclax

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Eligibility Screening: All patients must be enrolled on APEC14B1 and consented to Eligibility Screening (Part A) prior to treatment and enrollment on AALL2321. - Age: 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. - Diagnosis: Patients must have newly diagnosed B-acute lymphoblastic leukemia (B-ALL, 2017 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.

Exclusion Criteria:

- Patients with Down Syndrome. - Patients with secondary B-ALL that developed after treatment of a prior malignancy with cytotoxic chemotherapy. - Prior therapy: 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.

Conditions & Interventions

Conditions:
Blood Disorders, Cancer, Children's Health
Keywords:
ALL, KMT2A-G, KMT2A-R, KMT2A-Rearranged, Newly Diagnosed Acute Lymphoblastic Leukemia

More Information

Description: To evaluate the addition of two cycles of blinatumomab for all infants with newly diagnosed ALL and will evaluate in a randomized manner the safety, tolerability, and early activity of venetoclax in infants with KMT2A-R ALL.
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