COG AALL2121: A Phase 2 study of SNDX-5613 in combination with chemotherapy for patients with relapsed or refractory KMT2A-rearranged infant leukemia

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

1. Age: Patients must be 1 month to less than 6 years old at the time of study enrollment and must have had initial diagnosis of leukemia less than 2 years old. 2. Diagnosis: Patients must have KMT2A-rearranged acute lymphoblastic leukemia (ALL), acute leukemia of ambiguous lineage (ALAL), or mixed phenotype acute leukemia (MPAL), which is determined to be refractory or in first marrow relapse. 3. Disease status: First relapse, refractory or failure to achieve remission 4. See link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

1. Patients with isolated extramedullary leukemia. 2. Patients diagnosed with Down syndrome.

Conditions & Interventions

Conditions:
Cancer
Keywords:
ALAL, ALL, leukemia, MPAL, relapse

More Information

Description: This phase II trial tests the safety and best dose of revumenib when given together with chemotherapy, and how well the treatment regimen works for infants and young children with leukemia that has come back (relapsed) or does not respond to treatment (refractory) and is associated with a KMT2A (MLL) gene rearrangement (KMT2A-R). Revumenib is an oral medicine that directly targets the changes that occur in a cell with a KMT2A rearrangement and has been shown to specifically kill these leukemia cells in test tubes and animals. Drugs used in chemotherapy, such as vincristine, prednisone, asparaginase, fludarabine and cytarabine work in different ways to stop the growth of cancer cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. This trial is being done to find out if the combination of revumenib and chemotherapy may help to treat the cancer cells better than either treatment alone.
Study Contact: Allison Fullenkamp - fulle631@umn.edu
Principal Investigator: Peter Gordon
Phase: PHASE2
IRB Number: STUDY00021176