First-in-human Study of a New Treatment (4A10) for Patients With Relapsed or Hard-to-treat Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma, Focused on Safety and How the Drug Behaves in the Body and Early Signs of Effect.

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 18 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Key Inclusion Criteria:

1. Confirmed diagnosis of T/B-ALL or T/B-LL
2. Relapsed or refractory disease without curative options
3. Adequate organ function and performance status

Key Exclusion Criteria:

1. Patients with CNS3 disease
2. Patients with DNA fragility syndromes (e.g., Fanconi, Bloom), trisomy 21 (Down Syndrome)
3. Prior exposure to anti-CD127 therapies
4. Uncontrolled infections

Conditions & Interventions

Interventions:
DRUG: 4A10
Conditions:
Lymphoblastic Lymphoma, Acute Lymphoblastic Leukemia ALL
Keywords:
Leukemia, Refractory, Relapsed

More Information

Description:
ALT-101 is a first-in-human Phase 1 clinical trial testing a new antibody drug called 4A10 in patients with relapsed or hard-to-treat acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma. 4A10 is a targeted therapy designed to recognize and attach to a specific protein (CD127) found on leukemia cells. Once it binds, it works in two ways: it blocks growth signals that help cancer cells survive, and it helps the immune system find and destroy those cancer cells. In this study, patients receive 4A10 through an intravenous (IV) infusion once a week. The main goal of the trial is to find out if the drug is safe, what dose can be given, and how the body processes it. Researchers will also look for early signs that the treatment may be working. The study starts with small groups of patients receiving increasing doses to carefully monitor safety. Each patient is closely observed during the first treatment cycle (about 4-6 weeks) to watch for side effects. If the treatment is helping and is well tolerated, patients may continue treatment for up to six cycles. Overall, this study is an early step in testing a new, targeted immune-based therapy for difficult-to-treat blood cancers.

Contact(s): - cancer@cchmc.org
Principal Investigator:
Principal Investigator ID:
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IRB Number:
System ID: NCT07586618