A Study of Fludarabine Dosing in Children and Young Adults With B-cell Acute Lymphoblastic Leukemia

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Patients with B-ALL and eligible to receive commercial tisagenlecleucel.
- Patient's weight > 9 kg at time of lymphodepleting chemotherapy
- Adequate organ function at time of LD is required and is defined:
    - Hepatic: Serum bilirubin ≤ 2 mg/dL, unless benign congenital hyperbilirubinemia
    - Hepatic: AST and ALT < 5x the upper limit of normal for age, unless thought to be leukemic disease-related
    - Renal: Calculated glomerular filtration rate (GFR) ≥ 70 ml/min/1.73m^2. (based on Schwartz formula GFR (mL/min/1.73 m²) = (36.2 × Height in cm) / Creatinine in mg/dL
    - Cardiac: LVEF ≥ 50% by multi-gated acquisition scan (MUGA), resting echocardiogram, or cardiac magnetic resonance imaging (MRI) within 6 weeks of screening
    - Pulmonary: Oxygen saturation as recorded by pulse oximetry of ≥ 90% on room air
- Adequate performance status:
    - Age ≥ 16 years: ECOG ≤ 1 or Karnofsky > 60% at treatment
    - Age < 16 years: Lansky ≥ 60% at treatment
- Willing to participate as research subject and provide written informed consent from parents/legal representative, patient, and age-appropriate assent as appropriate before any study specific screening procedures are conducted, according to local, regional or national law and legislation.

Exclusion Criteria:

- Have a known immediate or delayed hypersensitivity reaction or idiosyncrasy to the study drugs, or drugs chemically related to study treatment or excipients that contraindicate their participation, including fludarabine, cyclophosphamide and tisagenlecleucel.
- Patients with tisagenlecleucel that is deemed out of specification (OOS) will be excluded from this protocol
- Clinically significant active and uncontrolled infection confirmed by clinical evidence, imaging, or positive laboratory tests (e.g., blood cultures, PCR for DNA/RNA etc.)
- Patient/parent/guardian unable to give informed consent or unable to comply with the treatment protocol.
- Pregnant or lactating women

Conditions & Interventions

Interventions:
DRUG: Fludarabine, DRUG: Cyclophosphamide, DRUG: Fludarabine, BIOLOGICAL: CAR-T
Conditions:
B-cell Acute Lymphoblastic Leukemia
Keywords:
Fludarabine

More Information

Description:
The researchers are doing this study to find out whether PK-targeted fludarabine is an effective Lymphodepletion (LD) chemotherapy approach for people with relapsed/refractory B-cell acute lymphoblastic leukemia (B-ALL) who will receive tisagenlecleucel CAR T-cell therapy. The researchers will compare PK-targeted fludarabine dosing with standard fludarabine dosing to see which treatment approach is more effective. The researchers will also look at whether PK-targeted fludarabine dosing is feasible (practical), the side effects of the study treatment, and how the study treatment affects people's quality of life. The researchers will measure quality of life by having participants complete questionnaires.

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