Cytokine-Induced Memory-Like Natural Killer Cells (CIML-NK) for Relapsed & Refractory Acute Myeloid Leukemia (AML)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Of age ≥ 2 years of age at the time of study enrollment
- With AML diagnosed per 2016 WHO criteria (11)
- With relapsed or refractory AML in their bone marrow
- Refractory disease: Patients must have ≥ 5% blasts in the bone marrow after 2 courses of intensive induction treatment
- Relapsed disease: Patients must have ≥ 5% blasts in the bone marrow, or reappearance of blasts in the blood, within 6 months of initial CR
- With available haploidentical related donors. Donor specific antibody (DSA) testing will be done on the recipient prior to or upon enrollment.
- With performance level of ≥ 50% on Karnofsky scale for patients > 16 years of age and ≥ 50% on Lansky scale for patients ≤ 16 years of age

Exclusion Criteria:

- Disease: isolated central nervous system (CNS) disease, or isolated extramedullary disease, or diagnosis of acute promyelocytic leukemia (APML). Patients with extramedullary disease in combination with bone marrow disease are eligible for enrollment.
- Infectious Disease: Active uncontrolled infection
- Cardiac function: Systolic ejection fraction <45% by echocardiogram
- Pulmonary Function: Oxygen saturation <92% on room air
- Hepatic function: Total bilirubin > 2mg/dL, AST and ALT more than three times the upper limit of normal
- Concomitant medications: receiving either >10mg prednisone equivalent daily, or >0.5mg/kg prednisone equivalent daily, whichever is less
- Concomitant investigational treatments: receiving other investigational therapies
- Known allergy or hypersensitivity reaction to IL-2 injections
- Pregnant or breastfeeding women will not be entered on this study due to risks of fetal and teratogenic adverse events with lymphodepleting chemotherapy. Pregnancy tests must be obtained for female patients. Males or females of reproductive potential may not participate unless they have agreed to use an effective contraceptive method while on study treatment and for six months following completion. Effective contraceptive methods include oral contraceptive pills, patches, or injections, intrauterine devices, having a tubal ligation, having a partner who has had a vasectomy, or not having sex.

Conditions & Interventions

Interventions:
DRUG: CIML-NK Cells
Conditions:
Acute Myeloid Leukemia

More Information

Description:
The objective of this study is to demonstrate that cytokine-induced memory-like natural killer cells can be generated from donor cells and infused safely into patients with relapsed or refractory acute myeloid leukemia (AML). A secondary objective is to assess efficacy of the CIML-NK cells in treating AML.

Contact(s): Caitlin Cottrell - caitlin.cottrell@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE1
IRB Number:
System ID: NCT05580601