

## The Pediatric Acute Leukemia (PedAL) Screening Trial - A Study to Test Bone Marrow and Blood in Children With Leukemia That Has Come Back After Treatment or Is Difficult to Treat - A Leukemia & Lymphoma Society and Children's Oncology Group Study

Status: RECRUITING

### Eligibility Criteria

Sex: ALL

Age: Up to 22 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Patients must be less than 22 years of age at the time of study enrollment
- Patient must have one of the following at the time of study enrollment:
  - Patient has known or suspected relapsed/refractory (including primary refractory) AML as defined in protocol
  - This includes isolated myeloid sarcoma
  - Patient has known or suspected relapsed/refractory (including primary refractory) myeloid leukemia of Down syndrome (ML-DS)
  - Patient has known or suspected relapsed ALL as defined in protocol that meets one of the following criteria:
    - Second or greater B-ALL medullary relapse, excluding KMT2Ar
    - Any first or greater B-ALL medullary relapse involving KMT2Ar
    - Any first or greater T-ALL medullary relapse with or without KMT2Ar
  - Patient has known or suspected relapsed/refractory (including primary refractory) mixed phenotype acute leukemia (MPAL) as defined in protocol
  - Patient has known or suspected de novo or relapsed/refractory (including primary refractory) treatment-related AML (t-AML)
  - Patient has known or suspected de novo or relapsed/refractory (including primary refractory) myelodysplastic syndrome (MDS) or treatment-related myelodysplastic syndrome (t-MDS)
  - Note: Relapsed/refractory disease includes stable disease, progressive disease, and disease relapse.
  - Patient has known or suspected de novo or relapsed/refractory (including primary refractory) juvenile myelomonocytic leukemia (JMML)
  - Note: Relapsed/refractory disease includes stable disease, progressive disease, and disease relapse.
- All patients and/or their parents or legal guardians must sign a written informed consent
- All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

### Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection

Conditions:

Acute Lymphoblastic Leukemia, Acute Myeloid Leukemia, Acute Myeloid Leukemia Post Cytotoxic Therapy, Juvenile Myelomonocytic Leukemia, Mixed Phenotype Acute Leukemia, Myelodysplastic Syndrome, Myelodysplastic Syndrome Post Cytotoxic Therapy, Myeloid Leukemia Associated With Down Syndrome

### More Information

Description:

This study aims to use clinical and biological characteristics of acute leukemias to screen for patient eligibility for available pediatric leukemia sub-trials. Testing bone marrow and blood from patients with leukemia that has come back after treatment or is difficult to treat may provide information about the patient's leukemia that is important when deciding how to best treat it, and may help doctors find better ways to diagnose and treat leukemia in children, adolescents, and young adults.

Contact(s): - cancer@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE1

IRB Number:

System ID: NCT04726241

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