



COG AALL1621 - A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND#133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)

Status: Recruiting

# Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy

This study is NOT accepting health

volunteers

## **Inclusion Criteria:**

- 1 to 21 years old - must have B Acute Lymphoblastic Leukemia (B-ALL), or previously diagnosed B lymphoblastic lymphoma (B-LL) - Patients with one of the following: Second or greater relapse; Primary refractory disease with at least 2 prior induction attempts; First relapse refractory to at least one prior re-induction attempt; OR Any relapse after HSCT (Cohort 1 ONLY) - see link to clinicaltrials.gov for complete Inclusion and Exclusion criteria

## **Exclusion Criteria:**

- currently receiving another investigational drug - currently receiving or plan to receive other anti-cancer agents (except hydroxyurea, which may be continued until 24 hours prior to start of protocol therapy, and intrathecal chemotherapy)

## Conditions & Interventions

#### Interventions

Drug: Asparaginase Erwinia chrysanthemi, Procedure: Biospecimen Collection, Procedure: Bone Marrow Aspiration and Biopsy, Drug: Calaspargase Pegol, Drug: Cyclophosphamide, Drug: Cytarabine, Procedure: Diagnostic Imaging, Biological: Inotuzumab Ozogamicin, Drug: Leucovorin Calcium, Procedure: Lumbar Puncture, Drug: Methotrexate, Drug: Pegaspargase, Drug: Vincristine

#### Conditions:

Cancer

### Keywords:

B-LL, Recurrent B Acute Lymphoblastic Leukemia, Recurrent B Lymphoblastic Lymphoma. B-ALL

## More Information

**Description:** This phase II trial studies how well inotuzumab ozogamicin works in treating younger patients (≥1 year and < 22 years) with CD22 positive B acute lymphoblastic leukemia that has come back or does not respond to treatment. Immunotoxins, such as inotuzumab ozogamicin, are antibodies linked to a toxic substance and may help find cancer cells that express CD22 and kill them without harming normal cells.

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