Protocol Title: A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 18-39 Years) with Newly Diagnosed Precursor B-Cell ALL

Target Population: Patients between the ages of 18 to 39 Years with Newly Diagnosed Precursor B-Cell Acute Lymphoblastic Leukemia (ALL)

Summary: This partially randomized phase III trial studies the side effects of Inotuzumab Ozogamicin and how well it works when given with frontline chemotherapy in treating patients with newly diagnosed B-Cell ALL

Key Eligibility Criteria:
- **REGISTRATION ELIGIBILITY CRITERIA (STEP 1)**
  - Newly diagnosed patients with CD-22 positive B-Cell Acute Lymphoblastic Leukemia (WHO criteria) are eligible.
    - Burkitt type ALL NOT eligible.
    - BCR-ABL fusion transcript determined by FISH or RT-PCR or t(9;22)(q34;q11) by cytogenetics are NOT eligible.
  - No prior therapy except for limited treatment (< 7 Days) with Corticosteroids or Hydroxyurea and a single dose of intrathecal Cytarabine.
  - No prior therapy for Acute Leukemia except emergency therapy (Corticosteroids or Hydroxyurea) for Blast Cell Crisis, Superior Vena Cava Syndrome, or Renal Failure due to leukemic infiltration of the kidneys.
  - Single-dose intrathecal Cytarabine is allowed prior to registration or prior to initiation of systematic therapy for patient convenience.
    - Systemic chemotherapy must begin within 72 Hours of this intrathecal therapy.
  - Patients receiving prior steroid therapy are eligible for study.
  - ECOG Performance Status 0-2.
  - Patients with Down Syndrome are excluded from this study.
- **RANDOMIZATION ELIGIBILITY CRITERIA (STEP 2)**
  - Completion of remission induction therapy.
  - Patients with M2 marrow or better are eligible.
    - Patients with M3 or M4 marrow (> 25% lymphoblasts) will not be eligible to be randomized.
  - No ascites, effusions or significant edema.
  - Completion of first 12 Weeks (12+ Weeks) of maintenance therapy (Course V).
  - Patient has at least 24 Weeks (24+ Weeks) remaining before end of maintenance therapy (Course V).
  - Patient is in complete continuous first remission at entry into A041501-HO1.
  - Patient is receiving oral anti-metabolite chemotherapy during the maintenance phase of therapy.
  - Patient is able and willing to use the Medication Event Monitoring System (MEMS) TrackCap (e.g. not using a pillbox).

Contacts:
- **Principal Investigator:** Laura Finn, MD
- **Research Nurses (RN):** Elise Curry (elisemarie.curry@ochsner.org, ext. 28084)
  Stephanie Green (stephanie.green2@ochsner.org, ext. 23918)

For additional information: [https://clinicaltrials.gov/ct2/show/NCT03150693](https://clinicaltrials.gov/ct2/show/NCT03150693)