Inotuzumab Ozogamicin and Frontline Chemotherapy in Treating Young Adults With Newly Diagnosed B Acute Lymphoblastic Leukemia

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 39 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

REGISTRATION ELIGIBILITY CRITERIA (STEP 1) * Newly diagnosed patients with CD-22 positive B-cell acute lymphoblastic leukemia (WHO criteria) are eligible. Patients with Burkitt type ALL are NOT eligible * Patients who have BCR-ABL fusion transcript determined by fluorescence in situ hybridization (FISH) or real time-polymerase chain reaction (RT-PCR) or t(9;22)(q34;q11) by cytogenetics are not eligible and should be considered for enrollment on studies that incorporate imatinib during induction; please note: flow cytometry is to be performed at the local reference lab and must include assessment of CD20 and CD22 positivity, as well as CD29 and CD22 anti-positivity * 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; when indicated, leukapheresis or exchange transfusion is recommended to reduce the WBC * 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; the dose and duration of previous steroid therapy should be carefully documented on case report forms * Not pregnant and not nursing; for women of childbearing potential only, a negative urine or serum pregnancy test done =\< 7 days prior to registration is required * Eastern Cooperative Oncology Group (ECOG) performance status 0-2 * Patients with down syndrome are excluded from this study * Aspartate aminotransferase (AST), alanine aminotransferase (ALT) =\< 3 x upper limit of normal (ULN), unless suspected leukemic involvement of the liver * Direct bilirubin =\< 3 x upper limit of normal (ULN), unless suspected leukemic involvement of the liver * Calculated (calc.) creatinine clearance \>= 50 mL/min by Cockcroft-Gault RANDOMIZATION ELIGIBILITY CRITERIA (STEP 2) * Completion of remission induction therapy * Patients with M2 marrow or better are eligible; patients with M3 or M4 marrow (greater than 25% lymphoblasts) will not be eligible to be randomized * Rating: M0, M1; Blast Cells (%): 0-5.0 * Rating: M2; Blast Cells (%): 5.1-25.0 * Rating: M3; Blast Cells (%): \> 25-50 * Rating: M4; Blast Cells (%): \> 50.0 * The term "blast cell" includes any cell that cannot be classified as a more mature normal element, and includes "leukemic cells," pathologic lymphocytes, and stem cells * No ascites, effusions or significant edema * Absolute neutrophil count (ANC) \>= 1,000/mm\^3 * Platelet count \>= 100,000/mm\^3 * Total bilirubin =\< 1.5 x upper limit of normal (ULN), except for patients with known Gilbert's syndrome * Aspartate aminotransferase (AST) =\< 8 x upper limit of normal (ULN) * 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; treatment plan must call for the following doses of antimetabolites: 6MP 75 mg/m2/day orally; methotrexate (MTX) 20 mg/m2/week orally (modification of 6 MP or MTX dosing based on laboratory or clinical parameters is acceptable) * Patient is able and willing to use the Medication Event Monitoring System (MEMS) TrackCap (e.g. not using a pillbox)

Conditions & Interventions

Interventions:

DRUG: Allopurinol, DRUG: Cytarabine, DRUG: Daunorubicin Hydrochloride, DRUG: Vincristine Sulfate, DRUG: Dexamethasone, DRUG: Pegylated L-Asparaginase, DRUG: Methotrexate, PROCEDURE: Bone Marrow Aspiration and Biopsy, DRUG: Cyclophosphamide, DRUG: Mercaptopurine, BIOLOGICAL: Rituximab, DRUG: Doxorubicin, DRUG: Thioguanine, BIOLOGICAL: Inotuzumab Ozogamicin, OTHER: Laboratory Biomarker Analysis

Conditions:

B Acute Lymphoblastic Leukemia

More Information

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