Inotuzumab Ozogamicin and Post-Induction Chemotherapy in Treating Patients With High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and B-LLy

Status: RECRUITING

Eligibility Criteria

Age: 1 year to 25 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* B-ALL and MPAL patients must be enrolled on APEC14B1 and consented to eligibility studies (Part A) prior to treatment and enrollment on AALL1732. Note that central confirmation of MPAL diagnosis must occur within 22 days of enrollment for suspected MPAL patients. If not performed within this time frame, patients will be taken off protocol. * APEC14B1 is not a requirement for B-LLy patients but for institutional compliance every patient should be offered participation in APEC14B1. B-LLy patients may directly enroll on AALL1732. * Patients must be \> 365 days and \< 25 years of age * White blood cell count (WBC) criteria for patients with B-ALL (within 7 days prior to the start of protocol-directed systemic therapy): * Age 1-9.99 years: WBC \>= 50,000/uL * Age 10-24.99 years: Any WBC * Age 1-9.99 years: WBC \< 50,000/uL with: * Testicular leukemia * CNS leukemia (CNS3) * Steroid pretreatment. * White blood cell count (WBC) criteria for patients with MPAL (within 7 days prior to the start of protocol-directed systemic therapy): * Age 1-24.99 years: any WBC NOTE: Patients enrolled as suspected MPAL but found on central confirmatory testing to have B-ALL must meet the B-ALL criteria above (age, WBC, extramedullary disease, steroid pretreatment) to switch to the B-ALL stratum before the end of induction. * Patient has newly diagnosed B-ALL or MPAL (by World Health Organization \[WHO\] 2016 criteria) with \>= 25% blasts on a bone marrow (BM) aspirate; * OR If a BM aspirate is not obtained or is not diagnostic of acute leukemia, the diagnosis can be established by a pathologic diagnosis of acute leukemia on a BM biopsy; * OR A complete blood count (CBC) documenting the presence of at least 1,000/uL circulating leukemic cells if a bone marrow aspirate or biopsy cannot be performed. * Patient has newly diagnosed B-LLy Murphy stages III or IV. * Patient has newly diagnosed B-LLy Murphy stages I or II with steroid pretreatment. * Note: For B-LLy patients with tissue available for flow cytometry, the criterion for diagnosis should be analogous to B-ALL. For tissue processed by other means (i.e., paraffin blocks), the methodology and criteria for immunophenotypic analysis to establish the diagnosis of B-LLy defined by the submitting institution will be accepted. * Central nervous system (CNS) status must be determined prior to enrollment based on a sample obtained prior to administration of any systemic or intrathecal chemotherapy, except for steroid pretreatment and cytoreduction. It is recommended that intrathecal cytarabine be administered at the time of the diagnostic lumbar puncture. This is usually done at the time of the diagnostic bone marrow or venous line placement to avoid a second lumbar puncture. This is allowed prior to enrollment. Systemic chemotherapy must begin within 72 hours of this intrathecal therapy. * All patients and/or their parents or legal guardians must sign a written informed consent. * All institutional, Food and Drug Administration (FDA), and NCI requirements for human studies must be met.

Exclusion Criteria:

* Patients with Down syndrome are not eligible (patients with Down syndrome and B-ALL are eligible for AALL1731, regardless of NCI risk group). * With the exception of steroid pretreatment and steroid cytoreduction or the administration of intrathecal cytarabine, patients must not have received any prior cytotoxic chemotherapy for the current diagnosis of B-ALL, MPAL, or B-LLy or for any cancer diagnosed prior to initiation of protocol therapy on AALL1732. * Patients who have received \> 72 hours of hydroxyurea within one week prior to start of systemic protocol therapy. * Patients with B-ALL or MPAL who do not have sufficient diagnostic bone marrow submitted for APEC14B1 testing and who do not have a peripheral blood sample submitted containing \> 1,000/uL circulating leukemia cells. * Patients with acute undifferentiated leukemia (AUL) are not eligible. * For Murphy stage III/IV B-LLy patients, or stage I/II patients with steroid pretreatment, the following additional exclusion criteria apply: * T-lymphoblastic lymphoma. * Morphologically unclassifiable lymphoma. * Absence of both B-cell and T-cell phenotype markers in a case submitted as lymphoblastic lymphoma. * Patients with known Charcot-Marie-Tooth disease. * Patients with known MYC translocation associated with mature (Burkitt) B-cell ALL, regardless of blast immunophenotype. * Patients requiring radiation at diagnosis. * Female patients who are pregnant, since fetal toxicities and teratogenic effects have been noted for several of the study drugs. A pregnancy test is required for female patients of childbearing potential. * Lactating women who plan to breastfeed their infants while on study and for 2 months after the last dose of inotuzumab ozogamicin. * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of study participation. For those patients randomized to inotuzumab ozogamicin, there is a minimum of 8 months after the last dose of inotuzumab ozogamicin for females and 5 months after the last dose of inotuzumab ozogamicin for males.

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Bone Scan, DRUG: Calaspargase Pegol, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, DRUG: Cytarabine, DRUG: Daunorubicin Hydrochloride, DRUG: Dexamethasone, DRUG: Doxorubicin Hydrochloride, BIOLOGICAL: Inotuzumab Ozogamicin, DRUG: Leucovorin Calcium, PROCEDURE: Magnetic Resonance Imaging, DRUG: Mercaptopurine, DRUG: Methotrexate, DRUG: Pegaspargase, PROCEDURE: Positron Emission Tomography, DRUG: Prednisolone, OTHER: Questionnaire Administration, RADIATION: Radiation Therapy, RADIATION: Radiation Therapy, DRUG: Thioguanine, DRUG: Vincristine Sulfate
Conditions:
B Acute Lymphoblastic Leukemia, B Lymphoblastic Lymphoma, Central Nervous System Leukemia, Mixed Phenotype Acute Leukemia, Testicular Leukemia

More Information

Contact(s): Gwaltney, Lindsey - lbgwaltney@vcu.edu
Principal Investigator: Griffin, Jordyn
Phase: PHASE3
IRB
Number: HM20018568
System ID: NCT03959085
