

COG AALL1732: A Phase 3 Randomized Trial of Inotuzumab Ozogamicin (IND#:133494, NSC#: 772518) for Newly Diagnosed High-Risk B-ALL; Risk-Adapted Post-Induction Therapy for High-Risk B-ALL, Mixed Phenotype Acute Leukemia, and Disseminated B-LLy

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Not specified

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- patients must be > 365 days and < 25 years of age - participant has newly diagnosed B-ALL or MPAL with $\geq 25\%$ blasts on a bone marrow (BM) aspirate or newly diagnosed B-LLy - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- patients with Down syndrome are not eligible - patients with acute undifferentiated leukemia (AUL) are not eligible - 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. - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:

Procedure: Biospecimen Collection, Biological: Blinatumomab, 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, Drug: Prednisone, Other: Questionnaire Administration, Radiation: Radiation Therapy, Radiation: Radiation Therapy, Drug: Thioguanine, Drug: Vincristine Sulfate

Conditions:

Cancer

Keywords:

B Acute Lymphoblastic Leukemia, B Lymphoblastic Lymphoma, Leukemia, Testicular Leukemia

More Information

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Phase: PHASE3

IRB Number: SITE00000723

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