Studying the Effect of Levocarnitine in Protecting the Liver From Chemotherapy for Leukemia or Lymphoma

Status: RECRUITING

Eligibility Criteria

Age: 15 years to 40 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* \>= 15 and \< 40 years at time of diagnosis * Newly diagnosed B-ALL, T-ALL, lymphoblastic lymphoma (LLy), or mixed-phenotype acute leukemia/lymphoma (MPAL) * Note: Philadelphia chromosome (PH)+ and PH-like acute leukemia are eligible (use of tyrosine kinase inhibitors \[TKI\] or CRLF2- targeted concomitant medication must be documented, if used) * Conjugated bilirubin =\< 1.5 x upper limit of normal (ULN) for age, regardless of baseline bilirubin (within 7 days prior to enrollment), and * Serum glutamate pyruvate transaminase (SGPT) (ALT) =\< 225 U/L (=\< 5x ULN) (within 7 days prior to enrollment), and * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L and serum glutamic oxaloacetic transaminase (SGOT) (AST) to 50 U/L regardless of baseline * SGOT (AST) =\< 250 U/L (=\< 5x ULN) (within 7 days prior to enrollment) * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L and SGOT (AST) to 50 U/L regardless of baseline * For patients receiving ursodiol prior to enrollment, laboratory values must meet above criteria off ursodiol for 7 days * PEDIATRIC PATIENTS (AGE 15-17 years): * A 24-hour urine creatinine clearance \>= 30 mL/min/1.73 m\^2 (within 7 days prior to enrollment) OR * A glomerular filtration rate (GFR) \>= 30 mL/min/1.73 m\^2. GFR must be performed using one of the following methods (within 7 days prior to enrollment): * 1\. Estimated GFR (eGFR) \>= 30 mL/min/1.73 m\^2. * An online calculator is available through the National Kidney Foundation at https://www.kidney.org/professionals/kdoqi/gfr_calculatorped * 2\. Measured GFR \>= 30 mL/min/1.73 m\^2 (any age). If measured GFR is used, it must be performed using direct measurement with a nuclear blood sampling method or small molecule clearance method (iothalamate or other molecule per institutional standard). * ADULT PATIENTS (AGE 18 YEARS OR OLDER): Creatinine clearance \>= 30 mL/min, as estimated by the Cockcroft and Gault formula or a 24-hour urine collection (within 7 days prior to enrollment). Estimated creatinine clearance is based on actual body weight * An online calculator is available through the National Kidney Foundation at https://www.kidney.org/professionals/kdoqi/gfr_calculatorcoc * Berlin-Frankfurt-Munich (BFM), Children's Oncology Group (COG), or C10403-based Induction regimen and must be inclusive of \>= 1 dose of pegaspargase or calaspargase pegol, and * First dose of asparaginase must be planned within the first week of induction therapy, and * Dose of pegaspargase or calaspargase pegol must be \>= 1,000 IU/ m\^2 (dose-capping permitted per primary regimen) * Note: Co-enrollment on a therapeutic consortia trial is not required * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

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Exclusion Criteria:

* Down syndrome * Known inherited or autoimmune liver disease impacting conjugated bilirubin (e.g., Alagille syndrome, primary sclerosing cholangitis, other) * Known biopsy (or imaging) proven severe liver fibrosis (Batts-Ludwig \>= stage 3) * Unable to tolerate oral formulation of study drug at enrollment * Patients who received chemotherapy or treatment for a prior malignancy are not eligible * The following are permitted: steroid prophase, hydroxyurea, or other cytoreduction prior to initiation of Induction chemotherapy (must be documented) and chemotherapy for current diagnosis (i.e. initiation of Induction therapy within enrollment window). Chemotherapy prior to enrollment for treatment of a non-malignancy (e.g., steroid or methotrexate for autoimmune disease) is also permitted and must be documented * Female patients who are pregnant since fetal toxicities and teratogenic effects in humans are unknown for study drug. A pregnancy test is required for female patients of childbearing potential * Lactating females who plan to breastfeed their infants * Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their study participation

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, DRUG: Calaspargase Pegol, DIETARY_SUPPLEMENT: Levocarnitine, DRUG: Pegaspargase, OTHER: Quality-of-Life Assessment

Conditions:
B Acute Lymphoblastic Leukemia, B Acute Lymphoblastic Leukemia With t(9,22)(q34.1,q11.2), BCR-ABL1, B Acute Lymphoblastic Leukemia, BCR-ABL1-Like, Lymphoblastic Lymphoma, Mixed Phenotype Acute Leukemia, T Acute Lymphoblastic Leukemia

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT05602194
