

Testing Whether High Dose Chemotherapy and Infusion of the Patients' Own Stem Cells Improves Survival in Patients With Peripheral T-cell Lymphoma Who Achieved a Complete Response at the End of the Initial Chemotherapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patient must be 18 to 75 years of age * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-2 * Patient must have histologically proven peripheral T-cell lymphoma (PTCL) in one of the following categories: * Anaplastic large cell lymphoma (ALCL) ALK-negative * Angioimmunoblastic T-cell lymphoma (AITL) * Nodal PTCL with follicular helper T cell (TFH) phenotype * Peripheral T-cell Lymphoma not otherwise specified (PTCL-NOS) * Patient must have undergone induction treatment with an anthracycline based chemotherapy. * NOTE: Patients who discontinued anthracycline during treatment are eligible as long as they received at least one dose and achieved complete remission * Patient must have achieved radiologic complete remission following induction therapy as defined by the Lugano criteria with a Deauville score between 1-3 by PET-CT * NOTE: There is no central review required. Confirmation of complete remission status is determined by the enrolling institution's review * NOTE: If a patient had a positive bone marrow biopsy at the time of initial diagnosis (pre-induction), a repeat biopsy must be completed post induction to confirm complete remission (CR) * Patient must be eligible for high dose chemotherapy and autologous stem cell transplant (ASCT) per the enrolling institutional guidelines at the transplant center and be ready to proceed with ASCT if randomized to the ASCT arm * Patient must not have active infection requiring intravenous systemic antimicrobial at time of randomization. Antibiotic prophylaxis is acceptable as long as the dose of the medication has been stable for at least 7 days prior to randomization * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the treatment regimens being used. All patients of childbearing potential must have a blood test or urine study within 14 days prior to randomization to rule out pregnancy. A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months) * Patient must not expect to conceive or father children by using accepted and effective method(s) of contraception or by abstaining from sexual intercourse during the treatment phase of the study and thereafter according to institutional guidelines * Absolute neutrophil count (ANC) \geq 1000/mcL (obtained \leq 14 days prior to protocol randomization) * Platelets \geq 75,000/mcL (obtained \leq 14 days prior to protocol randomization) * Total bilirubin \leq 1.5 x institutional upper limit of normal (ULN) (obtained \leq 14 days prior to protocol randomization) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT)(serum glutamic pyruvic transaminase [SGPT]) \leq 3.0 x institutional ULN (obtained \leq 14 days prior to protocol randomization) * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of randomization are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load

Conditions & Interventions

Interventions:

PROCEDURE: Autologous Hematopoietic Stem Cell Transplantation, OTHER: Best Practice, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Aspiration, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Computed Tomography, DRUG: High Dose Chemotherapy, PROCEDURE: Leukapheresis, PROCEDURE: Positron Emission Tomography, DRUG: Stem Cell Mobilization Therapy

Conditions:

Anaplastic Large Cell Lymphoma, ALK-Negative, Follicular Helper T-Cell Lymphoma, Follicular Helper T-Cell Lymphoma, Angioimmunoblastic-Type, Peripheral T-Cell Lymphoma, Not Otherwise Specified

More Information

Contact(s): Pamela Cogliano - ecog.rss@jimmy.harvard.edu

Principal Investigator:

IRB

Number:

System ID: NCT06724237

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