

Testing the Addition of an Anti-cancer Drug, Lenalidomide, to the Usual Combination Chemotherapy Treatment ("EPOCH") for Adult T-Cell Leukemia-Lymphoma (ATLL)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have histologically or cytologically confirmed CD2+, CD3+, or CD4+ acute, lymphoma or poor-risk chronic subtypes of ATLL including previously untreated or previously treated individuals who have received no more than 1 previous cycle of EPOCH, cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP), or cyclophosphamide, doxorubicin, vincristine, prednisone, and etoposide (CHOPE) * Patients previously treated with azidothymidine (AZT), interferon (IFN), bexarotene, or mogamulizumab are eligible. Patients with stable disease at high risk of relapse from prior non-combination chemotherapy containing treatment are eligible to participate * Documentation of HTLV infection by enzyme-linked immunosorbent assay (ELISA) in individuals with confirmation of HTLV-1 infection (by immunoblot or polymerase chain reaction [PCR]) or a consistent clinical picture (including two of three of: 1) CD4+ leukemia or lymphoma, 2) hypercalcemia, and/or 3) Japanese, Caribbean, or South American birthplace) is required for enrollment. Confirmation of HTLV-1 infection is required to continue the subject on protocol after the first cycle of therapy. Patients will be enrolled based on reports from local or referral labs (e.g., Mayo Clinic or LabCorp). Confirmation will be performed by Ratner Lab at Washington University, retrospectively, but this is not a Clinical Laboratory Improvement Amendments (CLIA) assay and is not reimbursed by insurance * Age ≥ 18 years * Because no dosing or adverse event (AE) data are currently available on the use of lenalidomide in combination with EPOCH in patients < 18 years of age, children are excluded from this study, but will be eligible for future pediatric trials * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 (Karnofsky ≥ 60%) * Absolute neutrophil count ≥ 1,000/mm³ unless decreased due to bone marrow (BM) involvement with lymphoma * Platelets ≥ 100,000/mm³ unless decreased due to BM involvement with lymphoma * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN), if potentially due to lymphoma, in the dose-expansion cohort, the first cycle may be given without lenalidomide and if transaminitis and bilirubinemia improves to meet parameters, participant may be enrolled * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) ≤ 2 x institutional ULN, if potentially due to lymphoma, in the dose-expansion cohort, the first cycle may be given without lenalidomide and if transaminitis and bilirubinemia improve to meet parameters, participant may be enrolled * Creatinine ≤ institutional ULN OR glomerular filtration rate (GFR) ≥ 60 mL/min/1.73 m² for participants with creatinine levels above institutional normal * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months 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 * Patients with treated brain metastases are eligible if follow-up brain imaging after central nervous system (CNS)-directed therapy shows no evidence of progression * Patients with new or progressive brain metastases (active brain metastases) or leptomeningeal disease are eligible if the treating physician determines that immediate CNS specific treatment is not required and is unlikely to be required during the first cycle of therapy * 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 * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * Patients must have a life expectancy > 12 weeks * Patients must have no serious active infection requiring therapy at the time of study entry * Patients must not require the concurrent use of chemotherapy, interferon, zidovudine, arsenic, radiation therapy, or other specific anti-tumor therapy, during the course of this study * The effects of lenalidomide on the developing human fetus are unknown. Immunodulatory derivative (immunomodulatory imide drug [IMiD]) agents as well as other therapeutic agents used in this trial are known to be teratogenic. Females of child-bearing potential (FCBP) must have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL within 10-14 days prior to, and again within 24 hours of starting lenalidomide, and must either commit to continued abstinence from heterosexual intercourse or begin two acceptable methods of birth control, one highly effective method and one additional effective method at the same time, at least 28 days before she starts taking lenalidomide. FCBP must also agree to ongoing pregnancy testing. Men must agree to use a latex condom during sexual contact with a FCBP even if they have had a successful vasectomy. All patients must be counselled at a minimum of every 28 days about pregnancy precautions and risk of fetal exposure. Should a woman become pregnant or suspect she is pregnant while she or her partner are participating in this study, she should inform her treating physician immediately. FCBP must use adequate contraception for at least 28 days after discontinuation from study. Men treated or enrolled on this protocol must also agree to use adequate contraception prior to the study, for the duration of study participation, and for at least 28 days after discontinuation from study * Ability to understand and the willingness to sign a written informed consent document. Participants with impaired decision-making capacity (IDMC) who have a legally-authorized representative (LAR) and/or family member available will also be eligible

Exclusion Criteria:

* Patients that have received prior IMiDs for treatment of ATLL * Patients who have had chemotherapy or radiotherapy within 4 weeks (6 weeks for nitrosoureas or mitomycin C) prior to entering the study * Patients who have not recovered to grade 1 or better from AEs due to prior anti-cancer therapy (not including cycle 1 of EPOCH, CHOP, or CHOPE if received off protocol) within 14 days prior to enrollment, with the exception of alopecia * Patients who are receiving any other investigational agents or have received them within 14 days prior to enrollment * History of allergic reactions attributed to compounds of similar chemical or biologic composition to lenalidomide or other agents used in study. Anaphylactic reactions including death have been reported with cyclophosphamide. Possible cross-sensitivity with other alkylating agents can occur * Patients unable to take aspirin or prophylactic doses of low molecular weight heparin or direct oral anticoagulants * Patients with urinary outflow obstruction (contraindication for cyclophosphamide) * Patients with any form of demyelinating disease should not be given vincristine sulfate injection * Patients with uncontrolled intercurrent illness * Patients with psychiatric illness/social situations that would limit compliance with study requirements * Pregnant women are excluded from this study because lenalidomide is an IMiD agent with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with lenalidomide, breastfeeding should be discontinued if the mother is treated with lenalidomide. These potential risks may also apply to other agents used in this study

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Marrow Biopsy, PROCEDURE: Computed Tomography, DRUG: Cyclophosphamide, DRUG: Doxorubicin Hydrochloride, DRUG: Etoposide, DRUG: Lenalidomide, PROCEDURE: Positron Emission Tomography, DRUG: Prednisone, DRUG: Vincristine Sulfate

Conditions:

Acute Adult T-Cell Leukemia/Lymphoma, Adult T-Cell Leukemia/Lymphoma, Chronic Adult T-Cell Leukemia/Lymphoma, HTLV-1 Infection

More Information

MORE INFORMATION

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: PHASE1

IRB

Number:

System ID: NCT04301076

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