"A Phase II Trial of PET-Directed Therapy for Limited Stage Diffuse Large B-Cell Lymphoma (DLBCL)"

Protocol

SWOG S1001

Purpose

To assess the 5-year progression-free survival (PFS) rate in patients with newly diagnosed limited stage diffuse large B-cell lymphoma using PET/CT scan to direct therapy after 3 cycles of R-CHOP

Investigator

Dr. Roberto Martinez

Eligibility

Initial Registration (Step 1)

-Patients must have biopsy-proven de-novo Diffuse Large B-cell Lymphoma. Patients with primary mediastinal lymphoma or testicular lymphoma are not eligible.
-Patients with prior or simultaneous diagnosis of indolent lymphoma are not eligible. Post-transplant lymphoproliferative disorder with DLBCL morphology is ineligible.
-Patients must have non-bulky Stage I or II disease by Ann Arbor classification. This staging excludes FDG-PET evaluation.
-Patients who have Stage I or II non-bulky disease based on diagnostic CT scan, but are upstaged to Stage III or IV based on FDGPET evaluation are also eligible. Stage and bulk are assigned using measurements obtained prior to biopsy.
-Patients must have a diagnostic quality contrast-enhanced CT scan of the chest, abdomen and pelvis AND baseline FDG-PET scan performed within 28 days prior to registration. Low resolution "localization" CT scans performed as part of a combined PET/CT scan are not adequate for enrollment or response determination on this protocol. If the patient has an allergy to CT contrast, then a non-enhanced CT will be acceptable.
-Patients must not have clinical evidence of central nervous system involvement by lymphoma, since proposed treatment would not be able to address it adequately. Any laboratory or radiographic tests performed to assess CNS involvement must be negative and must be performed within 42 days prior to registration.
-Patients may have either measurable or evaluable limited-stage DLBCL.
-Patients rendered free of measurable or evaluable disease by virtue of biopsy (resection) are also eligible. NOTE: If patient has measurable disease it must be documented on the Lymphoma Baseline Tumor Assessment Form. All
measurable disease must be assessed within 28 days prior to registration. -Patients with nonmeasurable disease with or without measurable disease must have all non-measurable disease assessed within 42 days prior to registration.
-Patients must have a unilateral or bilateral bone marrow biopsy performed within 42 days

prior to registration.
-Patients must have passed their 18th birthday.
-Patients must not have received prior chemotherapy, radiation, or antibody therapy for lymphoma.
-Patients must have a Zubrod performance status of 0 - 2
-No other prior malignancy is allowed except for the following: adequately treated in situ cancers (Stage 0), adequately treated basal cell or squamous cell skin cancer, adequately treated Stage I or II cancer from which the patient has been in complete remission, or any other cancer from which the patient has been disease-free for at least 5 years.

SECOND REGISTRATION (STEP 2)

-Patients must have completed 3 cycles of R-CHOP with no evidence of disease progression.
-Interim PET/CT scans must have been submitted for centralized review
-If PET-negative based on the returned results from centralized review, patients must be planning to begin further treatment within 35 days of the start of Cycle 3 of R-CHOP. If PET-positive based on the returned results from centralized review, it is important for patients to start IFRT as soon as possible after the end of Cycle 3 of R-CHOP. They should be planning to initiate IFRT followed by yttrium-90 ibritumomab tiuxetan within 35 days of the start of Cycle 3 of R-CHOP

For more information about this study and to inquire about eligibility, please contact the Research Staff at 410-601-6120.

Locations

Sinai Hospital of Baltimore
Northwest Hospital Center

ClinicalTrials.gov
Visit **ClinicalTrials.gov** for full clinical trial description