



AMC 034: Experimental Treatment EPOCH and Rituximab for HIV-Associated Non-Hodgkin's Lymphoma (NHL)

AMC 034 evaluates treatment with EPOCH chemotherapy and rituximab, a monoclonal antibody. This Phase II randomized study is being done to determine whether the combination of EPOCH and rituximab given at the same time is more effective than rituximab given after completion of EPOCH. In addition, the study will look at the effects of rituximab and EPOCH on immune function as well as on Epstein-Barr virus levels in the blood.

Rituximab is approved by the FDA for certain types of lymphoma that contain CD20. Preliminary results from a recent study in non-HIV infected elderly individuals with lymphoma suggest that chemotherapy given concurrently with rituximab was more effective than chemotherapy given alone. All drugs in the EPOCH regimen are approved by the FDA for the treatment of lymphoma.

EPOCH chemotherapy will be given by continuous intravenous infusion over 96 hours in this study because recent findings suggest this may be more effective. Study participants will receive the EPOCH infusion every 3 weeks for 4 to 6 treatments. Half of the participants will receive rituximab intravenously immediately prior to each EPOCH cycle and the other half will receive 6 rituximab treatments weekly for 6 consecutive weeks following their last EPOCH treatment.

Inclusion Criteria

- Men and women, age 18 and older, with documented HIV infection and previously untreated B-cell NHL who are interested and meet protocol eligibility. Lymphoma eligible: diffuse large B-cell, high-grade large cell immunoblastic, anaplastic large cell, high-grade B cell and Burkitt's or Burkitt-like lymphoma.
- Tumors must be CD20 positive.
- Evaluable and measurable disease: Stage I and IE or Stage II-IV.
- Adequate hematology and hepatic function: ANC ≥ 1000 cells/mm³, platelets $\geq 75,000$ /mm³ unless cytopenia secondary to lymphoma. Must be off colony stimulating factor at least 24 hours prior to chemotherapy. Transaminase ≤ 5 x ULN; total bilirubin < 2 unless secondary to hepatic infiltration with lymphoma or isolated hyperbilirubinemia associated with indinavir or other antiretrovirals.
- Creatinine < 2 unless due to lymphoma.
- Karnofsky Performance Status ≥ 50 .
- Negative pregnancy test. Pregnancy and fathering children must be avoided while in the study.
- Patients already receiving erythropoietin or G-CSF are eligible.
- Patients must have a left ventricular ejection fraction that is at or above the lower institutional limits of normal, as assessed by nuclear scan or EKG obtained within 12 weeks of study entry.
- May have lymphomatous meningitis (patients with a positive CSF cytology are eligible).

Exclusion Criteria

- Previous chemotherapy or radiotherapy for this lymphoma.
- Primary Central Nervous System Lymphoma (parenchymal brain or spinal cord tumor).
- Acute active HIV-associated opportunistic infection requiring antibiotic treatment. MAC is not excluded.
- Concurrent malignancy (excluding in situ cervical cancer, non-metastatic non-melanomatous skin cancer or KS not requiring systemic chemotherapy).
- Previous therapy with rituximab within 12 months.

AMC 034 is being conducted under the direction of Ronald Mitsuyasu MD at the UCLA CARE Center. AMC 034 is sponsored by the National Cancer Institute and coordinated by the AIDS Malignancy Consortium (AMC).

To find out more about this study, call Carrie at (310) 825-0854 or e-mail cderkowski@mednet.ucla.edu

Clinical AIDS Research & Education
UCLA CARE Center