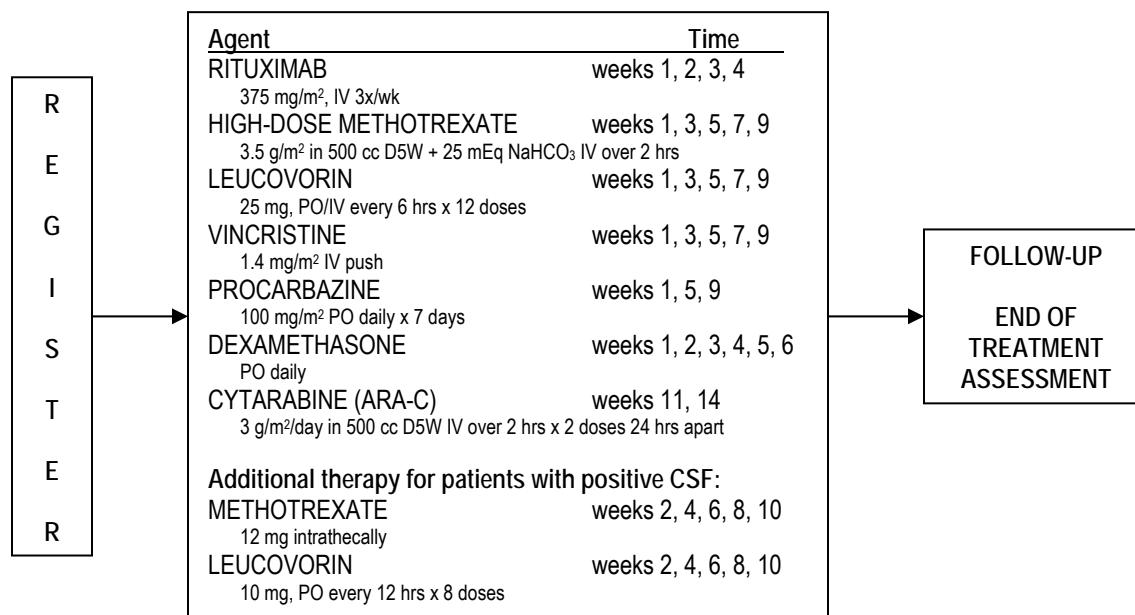


E1F05: Phase II Study of Rituximab Given in Conjunction with Standard Chemotherapy in Primary Central Nervous System (CNS) Lymphoma



MAJOR ELIGIBILITY CRITERIA:

- Must have histologic evidence of NHL by brain biopsy.
- OR
- Patients with an inconclusive biopsy or who are not biopsy candidates may be eligible, provided that they have a typical CT or MRI scan of the brain and meet at least one of the 2 additional criteria:
 - A positive CSF cytology for lymphoma or a monoclonal lymphoid population as defined by cell surface markers or immunoglobulin gene rearrangement studies.
 - Biopsy proven involvement of the vitreous or uvea if cells are apparent in the posterior chamber or vitreous on ophthalmological examination.
 - Must have bi-dimensionally measurable disease defined as a contrast enhancing tumor of at least 1cm² on the pretreatment MRI/CT scan. If an excisional, rather than a needle biopsy was done, measurable disease must be present on a post-operative scan. All scans must be obtained ≤ 4 weeks prior to registration.
 - Must be registered ≤ 4 weeks from histologic diagnosis. Scans or physical examinations used for tumor assessment must have been obtained within this same time period.
 - Must not have had any prior chemotherapy or radiation therapy for primary CNS lymphoma.
 - Must be HIV-1 negative.
 - Must not have systemic lymphoma.
 - Must have an AGC ≥ 1,500/mm³, platelets ≥ 100,000/mm³, bilirubin ≤ ULN, SGOT ≤ 2.0xULN, creatinine clearance ≥ 50cc/min. Must be obtained ≤ 4 weeks prior to registration.
 - Age ≥ 18 years with an ECOG performance status of ≤ 3.
 - Must not have concurrent malignancies, excluding basal cell carcinomas of the skin or any carcinoma *in situ*. Patients with prior malignancy who have been disease-free for ≥ 5 years are eligible, unless that malignancy was a NHL.
 - Must not have a pre-existing immunodeficiency, such as organ or BMT.
 - Must be tested for Hepatitis B surface antigen within 2 weeks of registration. Chronic carriers of Hepatitis B virus are excluded.

PRE-STUDY LABS AND TESTS:

≤ 4 weeks prior to registration

HIV test, CSF, ophthalmologic exam, CBC, diff., platelets, creatinine, electrolytes, CrCl, LFTS, cranial MRI/CT

≤ 2 weeks prior to registration

Beta-HCG (if applicable), hepatitis B test

FOR MORE INFORMATION CONTACT: Connie Sparks at (608)263-4511 or pager 5167