Cancer Research Consortium
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Fast Facts

CALGB 51101: A Randomized Phase II Trial of Myeloablative Versus Non-Myeloablative Consolidation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma

- Arm 1 and Arm 2 receive the same induction therapy (cycles 1-5). Each cycle will be 28 days in length.

- Restaging will occur after completion of induction cycle 5. Patients who achieve a complete response, complete response unconfirmed, partial response, or stable disease will proceed to consolidation therapy. Patients with progressive disease will be removed from protocol therapy.

- Patients will be put on Consolidation Arm 1 or Arm 2.

ELIGIBILITY CRITERIA

1. Diagnosis of primary CNS diffuse large B-cell lymphoma confirmed by one of the following:
   - Brain biopsy or resection
   - Cerebrospinal fluid
   - Vitreous fluid
2. Other Lymphomas
   - Patients must have no evidence or history of non-Hodgkin lymphoma (NHL) outside of CNS.
   - Patients must have no isolated ocular lymphoma.
3. Previous Treatment
   - Patients must have no prior chemotherapy or radiation therapy for lymphoma.
4. Age
   - Patients must be between the ages of 18 and 75 years.
5. Karnofsky Performance Scale
   - Patients must measure Karnofsky Performance Scale ≥ 30 (≥ 50 for patients ages 60-70).
6. Pregnancy and Nursing Status
   - Patients must be non-pregnant and non-nursing. Due to the unknown teratogenic potential of this regimen, pregnant or nursing patients may not be enrolled. Women of childbearing potential must have a negative serum or urine pregnancy test 10-14 days prior to registration. In addition, women and men of childbearing potential must commit to use an effective form of contraception throughout their participation in this study due to the teratogenic potential of the therapy utilized in this trial. Appropriate methods of birth control include abstinence, oral contraceptives, implantable hormonal contraceptives, or double barrier method (diaphragm plus condom).
7. HIV
   - Patients must have negative HIV serology.
8. Hepatitis
   - Patients must have negative HCV serology (unless HBsAb positive patient has recently received HBV vaccine, in this case HBcAb should be negative). All patients must be screened for hepatitis B infection before starting treatment. Those patients who test positive for hepatitis B should be closely monitored for evidence of active HBV infection and hepatitis during and for several months after rituximab treatment. PCNSL patients with a history of hepatitis B infections should be treated with entecavir or lamivudine (physician discretion for choice of drug) as antiviral prophylaxis to prevent hepatitis B reactivation.

9. Organ Transplant or Immunosuppressant Therapy
    - Patient must have no history of organ transplantation or ongoing immunosuppressant therapy.
10. Required Initial Laboratory Values:
    - ANC $\geq$ 1500/mcL
    - AST and ALT $\leq$ 2 x upper limit of normal (ULN)
    - Total Bilirubin $\leq$ 3mg/dL
    - Creatinine Clearance $\geq$ 50mL/min
    - Platelet Count $\geq$ 100,000/mcL

PRE-STUDY PARAMETERS

- Physical Exam, Med History, Weight, Height, Vitals, Performance Status, Neurological Examination
- CMP
- CBC
- CMP, LDH
- Serum or Urine BetaHCG
- HBsAg, HBsAb, HB core antibody
- HCV, HIV, CMV antibody
- Brain MRI with contrast
- Lumbar Puncture
- Ophthalmological Exam
- Testicular Ultrasound
- KPS
- Bone Marrow Aspirate and Biopsy
- PET/CT, CT, or MRI of chest/abd/pelvis
- Histological Review
- MMSE