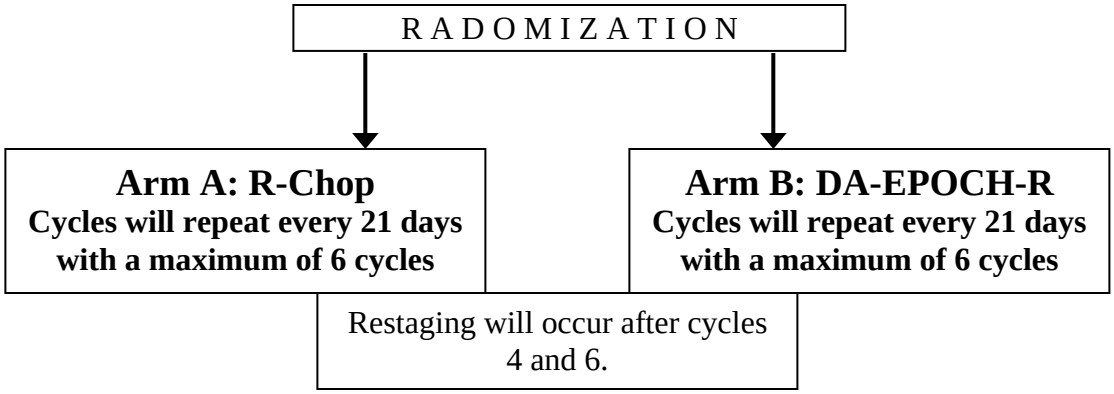
CALGB 50303: A Phase III Randomized Study of R-Chop versus Dose-Adjusted EPOCH-R with Molecular Profiling in Untreated DeNovo Diffuse Large B-cell Lymphomas



MAJOR ELIGIBILITY CRITERIA:

- Histologically documented de novo stage I medastinal (thymic) DLBCL or any stage II, III, or IV BLBCL
- Patients must have one of the following WHO histologic subtypes without evidence of indolent histological features in the tissue biopsy or bone marrow:
    - CD20+ diffuse large B-cell lymphoma (includes morphological variants: centroblastic; immunoblastic; T-cell/histiocyte rich; and anaplastic)
    - CD20+ mediastinal (thymic) large B-cell lymphoma
    - CD20+ intravascular large B-cell lymphoma
- No prior cytotoxic chemotherapy or rituximab
- Age ≥ 18 years
- ECOG performance status 0-2
- No active ischemic heart disease or congestive heart failure
- No known lymphomatous involvement of the CNS
- No known HIV disease
- Must be non-pregnant and non-nursing
- Required initial laboratory values (unless attributable to non-Hodgkin lymphoma)
    - ANC ≥ 1,000 / µL
    - Platelets ≥ 100,000 / µL
    - Creatinine ≤ 1.5 mg/dL OR CrCl ≥ 50 cc/min
    - Total Bilirubin ≤ 2 mg/dL (unless attributable to Gilbert's Disease)
- No active medical processes (uncontrolled bacterial or viral infection, bleeding) not related to their lymphoma
- No concurrent radiation therapy except for isolated CNS lesions

PRE-STUDY LABS AND TESTS:

≤ 16 days prior to registration:	H&P, CBC, Diff, Platelets, Serum Creatinine, BUN, AST, Alk Phos, Bilirubin, LDH, Total Protein, Albumin, HIV serology (if necessary), HBSAg and serology
≤ 28 days prior to registration:	Fresh Tumor Biopsy, Pharmacogenomic Sample, Heat scan (MRI preferred) & CSF exam (if risk factors), CT/MRI Scan Chest, Abd, and Pelvis,
≤ 42 days prior to registration:	EKG, LVEF, Bone Marrow Aspirate and Biopsy

≤ 30 days prior to start of therapy and prior to baseline excisional biopsy: PET/CT scan

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