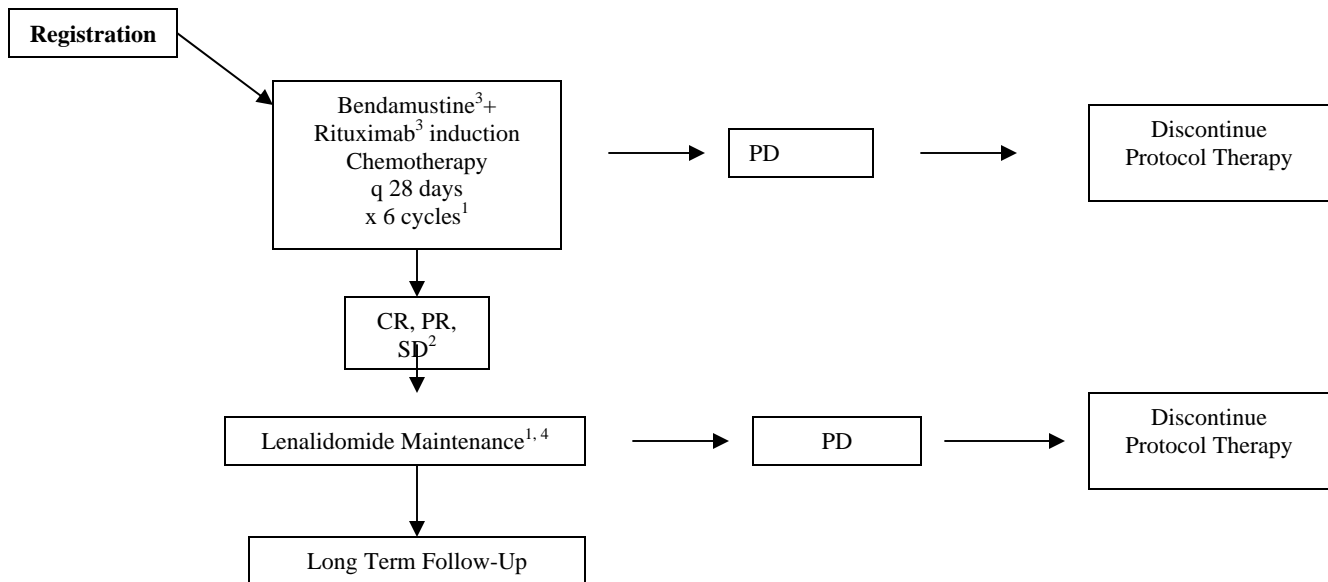


**HO08405 A Phase II Study of bendamustine and rituximab induction  
chemoimmunotherapy followed by maintenance lenalidomide in relapsed and refractory  
chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)**



- 1.) Restaging post C3 and C6 of induction and every 3 Months during lenalidomide maintenance.
- 2.) SD can continue to maintenance at investigator discretion.
- 3.) Dosing for induction therapy: Bendamustine 90 mg/m<sup>2</sup> IV days 1 and 2 every 28 days x 6 cycles;  
Rituximab 375 mg/m<sup>2</sup> IV day 1 every 28 days x 6 cycles
- 4.) Lenalidomide Maintenance dose: Lenalidomide 5 mg orally daily continuously for 12 months; dose escalation to 10 mg orally daily at 4 weeks in patients with acceptable toxicities.

**MAJOR ELIGIBILITY CRITERIA:**

- Histologically confirmed diagnosis of CLL/ SLL
- Patients must have documented relapsed or refractory CLL/SLL
- ECOG performance status of 0, 1, or 2
- Patients must have received ≥1 prior chemotherapy regimen for disease.
- In cases of SLL patients must have at least one bimensionally measurable lesion at least ≥1.5 cm measured in 1 dimension.
- ANC ≥ 1500/uL, Platelet count ≥100,000/uL,
- Must be disease free of prior malignancies for ≥2yrs with the exception of basal or squamous cell skin carcinoma
- Patients with neutrophils <1500/uL or platelets <100,000/uL with splenomegaly or extensive BM involvement as the etiology for their cytopenias are eligible
- Creatinine Clearance of ≥40mL/min
- No known HIV; No known CNS
- Age ≥ 18years
- Prior therapy with rituximab is permitted
- Must not have received >5 lines of prior therapy for their disease

**PRE-STUDY LABS AND TESTS:**

- \*≤ 4 weeks prior to registration: Hematology Profile, electrolytes, calcium, magnesium, phosphorus, glucose, albumin, total protein, uric acid, BUN, creatinine, LDH, β<sub>2</sub>-microglobulin, total bilirubin, AST, ALT, alk phos, Hepatitis B Surface antigen, TSH, serum pregnancy
- \* Within 6 weeks of enrollment: CT chest/abd/pelvis, PET (if clinically indicated), Bone Marrow Biopsy

**For more information call: Rachel Kirby (608) 263-7813**