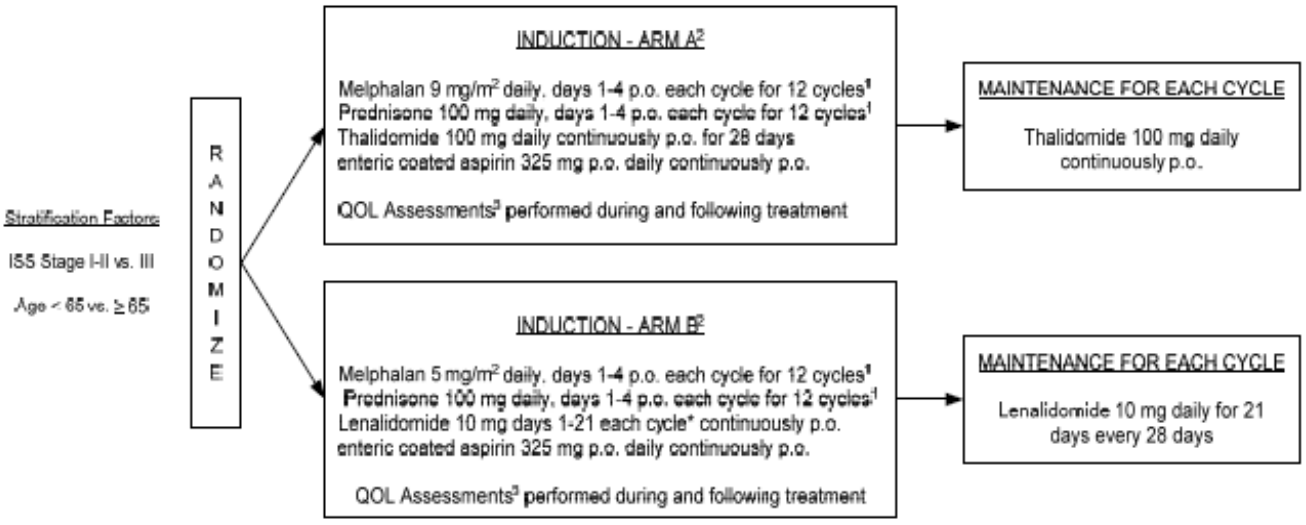
E1A06: An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) Versus Melphalan, Prednisone and Lenalidomide (Revlimid) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who Are Not Candidates for High-dose Therapy



MAJOR ELIGIBILITY CRITERIA:

- Patients must be diagnosed with symptomatic Multiple Myeloma, that was symptomatic at time of initial diagnosis.

For the original diagnosis of myeloma (see Appendix IV) patients should have met the following criteria at one point in their disease course:

- Bone marrow plasmacytosis with > 10% plasma cells or sheets of plasma cells or biopsy proven plasmacytoma.
- Patient must have had symptomatic disease at initial diagnosis that prompted the initiation of therapy as well as evidence of end-organ damage at the time of diagnosis namely; at least one of the following: anemia, hypercalcemia, bone disease (lytic bone lesions or pathologic fracture), or renal dysfunction.

NOTE: Patients with smoldering myeloma (serum m protein ≥3 gm/dL or bone marrow plasma cells ≥10% or greater plus no evidence of anemia, hypercalcemia, lytic bone lesions or renal dysfunction) and monoclonal gammopathy of undetermined significance (serum m protein <3 gm/dL and bone marrow plasma cells <10% or greater plus no evidence of anemia, hypercalcemia, lytic bone lesions or renal dysfunction) are not eligible

- Patients must be > 65 and have declined alternative treatment

  OR
- Patients who are > 18 < 65 are eligible if they are not a candidate for autologous stem cell transplantation in the opinion of the treating physician.

  OR
- Have declined transplant or other alternative treatment.
- ECOG performance status < 2.
- Patients must be previously untreated for myeloma, although prior treatment for myeloma with prednisone or dexamethasone for less than 4 weeks total dosing alone or in combination with thalidomide or lenalidomide for less than 2 weeks total dosing is allowable.
- Patients may be receiving bisphosphonates or growth factors (erythropoietin) for Multiple Myeloma. Although erythropoietin is allowed, it is strongly discouraged due to increased risk of thrombosis when employed alongside Thalidomide and/or lenalidomide therapy.
- Patients must be willing and able to take prophylaxis with either aspirin at 325 mg/day or alternative prophylaxis with either low molecular weight heparin or coumadin.
- Patients must not have uncontrolled inter-current illness that would limit compliance with the study including: Uncontrolled hypertension, Symptomatic congestive heart failure, Unstable angina, Uncontrolled cardiac arrhythmia, Uncontrolled psychiatric illness or social situation, Prior history of Stevens Johnson Syndrome,
- Patients must not have Grade 2 or higher peripheral neuropathy
- Patients must not have an active, uncontrolled infection.
- Female patients MUST NOT be pregnant or breastfeeding.
- Patients must not have had a second active malignancy requiring treatment within the last 2 years, with the exceptions of basal or squamous cell carcinoma of the skin, in situ carcinoma of the cervix.

PRE-STUDY LABS AND TESTS:

≤ 28 days prior to registration	CBC w/ diff, Alk Phos., ALT, AST, Calcium, Creatinine, Glucose, NA, K, T. Bili, Uric Acid, LDH, B2M, C-reactive Protein SPEP and UPEP(24hr)
≤ 42 weeks prior to registration	Bone marrow, Bone survey

FOR MORE INFORMATION CONTACT: ElizabethWagner at (608)265-3797 or pager 6928