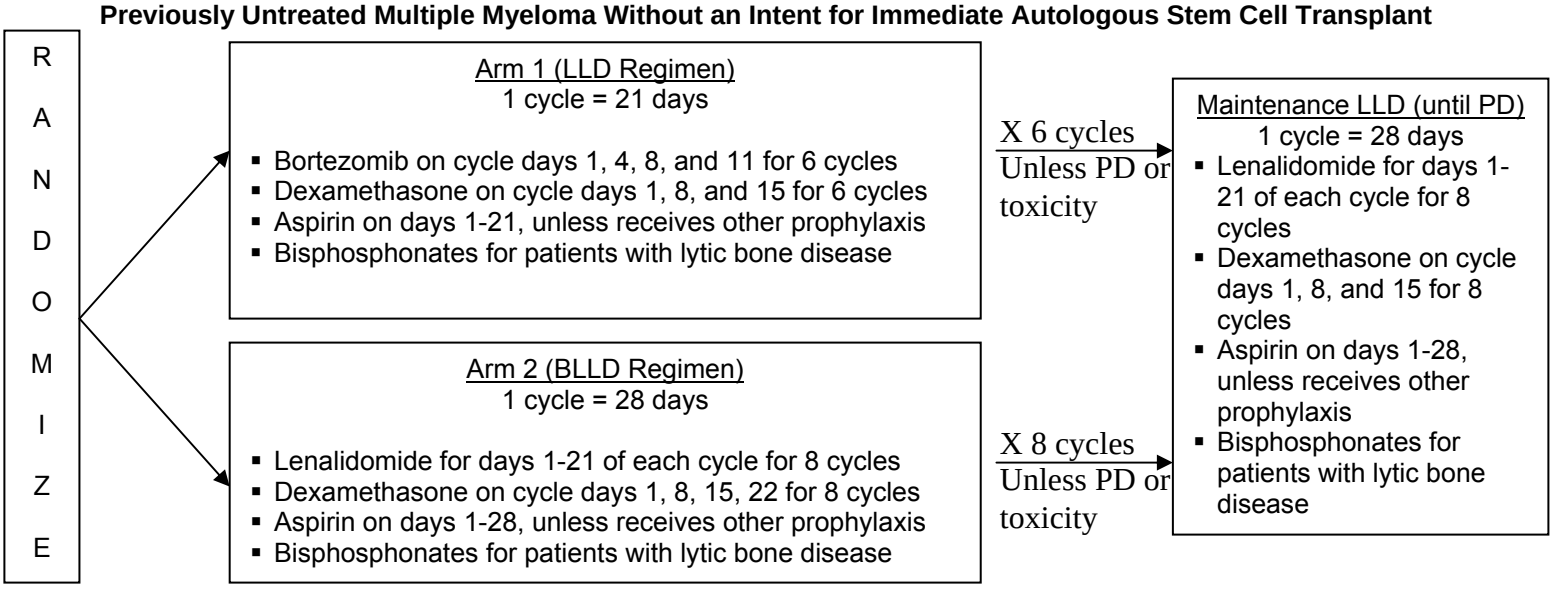
S0777: A Randomized Phase III Trial of Lenalidomide and Low Dose Dexamethasone (LLD) Versus Bortezomib, Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant



MAJOR ELIGIBILITY CRITERIA:

- Patients must be newly diagnosed with measurable Multiple Myeloma:
  - Measurable disease requires either 1g/dL serum M-spike or 200mg/24 hour urine M-spike
  - Patients with non-secretory disease may be eligible with elevated free light chains (≥ 10mg/dL)
- No prior chemotherapy; up to two weeks of steroids is permissible
- Prior palliative and/or localized radiation therapy is not permitted
- Local cytogenetics and FISH must be submitted prior to enrollment, patient must be offered participation in Myeloma Specimen Repository
- Must have adequate marrow function as indicated by Hgb > 9g/dL, platelets > 80,000cells/mm^3, ANC >1,000cells/$mm^{3;}$ unless biopsy-proven heavy-marrow involvement (30% cellularity, 50% plasma cells)
- Creatinine clearance (measured or calculated) > 30cc/min
- Must not have active, uncontrolled seizure disorder; must have had no seizures in the last 6 months
- Must not have uncontrolled hypertension, symptomatic congestive heart failure, unstable angina, uncontrolled cardiac arrhythmia, uncontrolled psychiatric illness/social situation, or prior history of Stevens Johnson Syndrome
- Age ≥ 18 years with an ECOG performance status of 0, 1, or 2; PS of 3 is allowable if it is the direct result of the patient's disease
- Must not have grade 2 or higher peripheral neuropathy or an active, uncontrolled infection
- Patients of childbearing potential must agree to use adequate contraception prior to study entry. Women must not be pregnant or breastfeeding

PRE-STUDY LABS AND TESTS:

≤ 42 days prior to randomization:	Metastatic bone survey, PFTs
≤ 28 days prior to randomization:	SPEP (including Albumin), quantitative IgG, IgA, and IgM, 24hr urine M-protein by UPEP, serum free light chains, serum M-protein by immunofixation, urine M-protein by immunofixation, BM aspirate and/or biopsy with % plasma cells and cytogenetics with FISH, B2M, C-reactive protein, LDH, ECG, serum pregnancy test (if applicable), creatinine, direct bili., ALT (SGPT), HIV-1. HIV-2, HTLV1, HIV-1 Ag, HSV, CMV
≤ 7 days prior to randomization:	CBC w/ differential, glucose, electrolytes

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