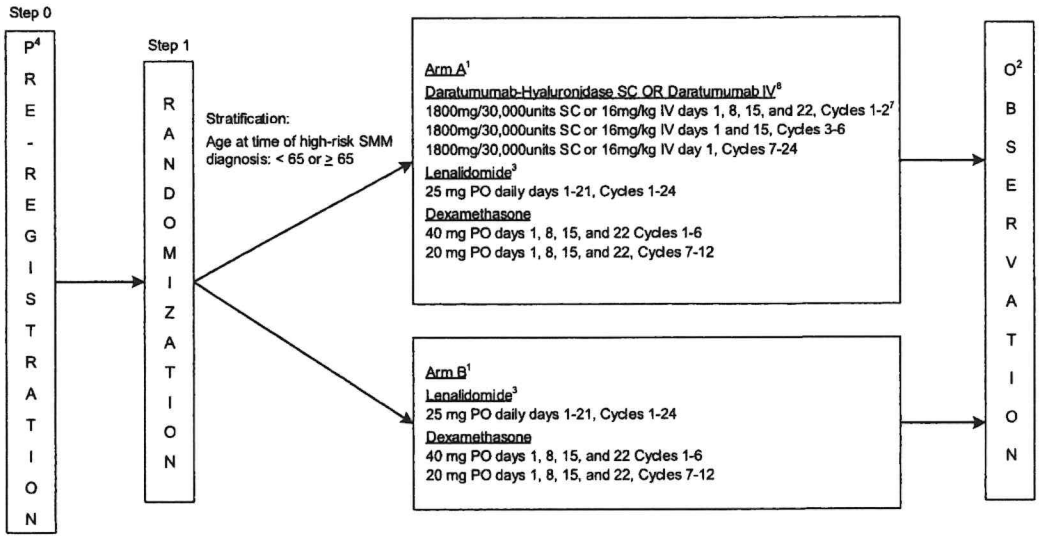
Rev. Add 1
Rev. Add 2

Schema



Accrual Goal: 288 patients with high-risk smoldering multiple myeloma.[5]

Cycle: 28 days

1. Peripheral blood stem cells for future transplants should be collected between cycles 4-6 of therapy. Therapy may be interrupted for up to 6 weeks to allow for PBSC collection. While collection following 4-6 weeks of therapy is strongly suggested, it is not required for protocol participation.
2. All patients, including those who discontinue protocol therapy early, will be followed for response until progression, even if non-protocol therapy is initiated, and for survival for 15 years from the date of randomization.
3. In patients with calculated (Cockroft-Gault) creatinine clearance of 30-59 ml/min, starting dose of lenalidomide should be reduced to 10 mg. If the clearance improves to ≥ 60 ml/min, the dose can be increased to 25 mg provided the patient has not experienced any of the toxicities that would require a dose reduction for lenalidomide.
4. Submission of pre-study specimens per patient consent.
5. Patients must be diagnosed within the past 12 months. See Section 3.2.2 for the definition of high-risk SMM.
6. Patients currently receiving IV daratumumab should cross over to SC daratumumab-hyaluronidase unless they do not tolerate daratumumab-hyaluronidase. Patients intolerant of SC daratumumab-hyaluronidase may remain on or cross over to IV daratumumab. Please refer to section 5.1.1 for daratumumab treatment details.
7. For patients receiving IV daratumumab, split-dosing schedule may be used for first IV infusion, and will consist of 8mg/kg given on Cycle 1, days 1 and 2 only