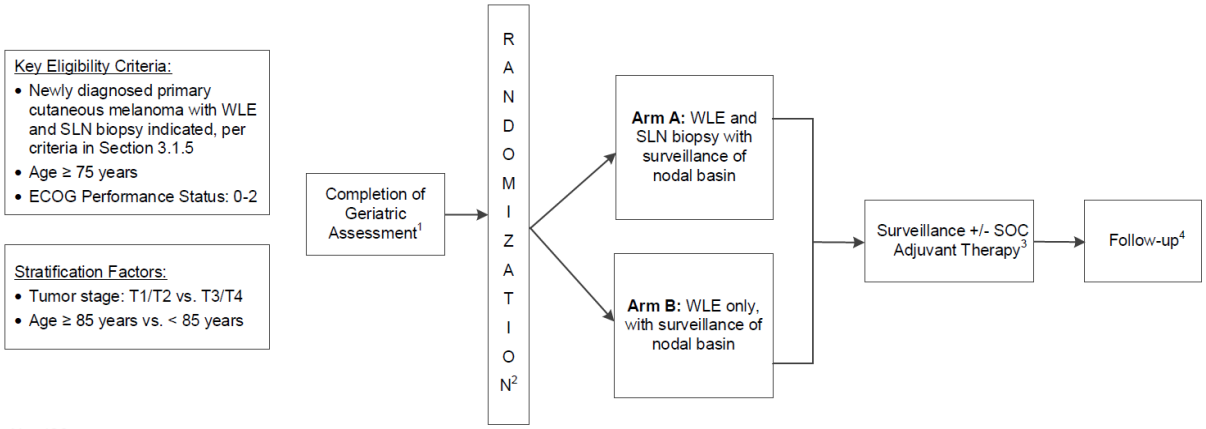
EA6244 - A RANDOMIZED PHASE III STUDY OF MANAGEMENT OF TREATMENT NAIVE PRIMARY MELANOMA IN ELDERLY PATIENTS

Eligibility Criteria

1. Patient must be ≥ 75 years of age.
2. Patient must have ECOG Performance Status of 0-2.
3. Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible.
4. Patient must have newly diagnosed primary cutaneous melanoma with wide local excision (WLE) and sentinel lymph node (SLN) biopsy indicated per the treating physician, pending definitive surgical management.
   NOTE: For WLE and SLN to be indicated, the patient must have either:
   - Pathologic features that include ≧Breslow 0.8 mm OR Breslow <0.8 mm determined at initial biopsy, with a positive margin, ulceration, lymphovascular invasion, perineural invasion or >1 mitosis/mm2
     OR
   - Risk of SLN metastasis of at least 5%, as calculated using the MIA Sentinel Node Metastasis Prediction Tool (See Appendix I).
5. Patient must be eligible for WLE and SLN biopsy. Patients for whom SLN biopsy would be contraindicated, difficult to perform (i.e., after prior surgery in the draining basin) or impossible (i.e., after prior lymphadenectomy for another cause) are not eligible.
6. Patient must be eligible for surgery and not have uncontrolled medical conditions that in the opinion of the medical or surgical oncologist precludes surgical management.
7. Patient must not have an active infection that precludes enrollment to this study in opinion of treating investigator.
8. Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months of randomization are eligible for this trial.
9. Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.
10. Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better.
11. Patient must be English speaking to be eligible for this study in order to complete the patient-reported outcomes (PROs). NOTE: Sites cannot translate the associated QOL forms.

Schema



N = 428
Randomization 1:1

1. The Geriatric Assessment must be administered after consent but prior to randomization. See Section 7.2 and Appendix II for instructions on accessing and administering the measures.
2. Assigned surgical intervention must occur within 45 calendar days after randomization. Delayed start of treatment due to unforeseen illness or hospitalization must not exceed an additional 21 days.
3. Surveillance visits will occur every 4 months (+/- 6 weeks) for the first 2 years post-randomization. Patients may receive adjuvant therapy if clinically indicated, at the investigator's discretion. Any adjuvant therapies are allowed, including both standard of care and investigational. Requirements for co-enrollment are outlined in Section 5.1.3.
4. Follow-up visits will occur every 6 months (+/- 6 weeks) from years 2-5, or after progression if it occurs prior to year 2, for a total of 5 years from randomization.