v.03/03/26

NCI National Clinical Trials Network

EA6244

ECOG-ACRIN cancer research group

Please Enroll Your Eligible Patients!

For Elderly Patients with Newly Diagnosed Melanoma

EA6244 Available Through ECOG-ACRIN Cancer Research Group

A Randomized Phase III Study of Management of Treatment Naive Primary Melanoma in Elderly Patients

Patient Population

See protocol Section 3 for complete eligibility criteria

- Age ≥ 75 years and ECOG PS 0-2
- Must have newly diagnosed primary cutaneous melanoma with wide local excision (WLE) and sentinel lymph node (SLN) biopsy indicated per treating physician, pending definitive surgical management; for WLE and SLN to be indicated, must have either:
  - ◊ Pathological 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 ≥ 5% per MIA Sentinel Node Metastasis Prediction Tool
- Must be eligible for WLE and SLN biopsy
  - ◊ Patients for whom SLN biopsy would be contraindicated, difficult to perform, or impossible are not eligible
- Must be eligible for surgery and not have uncontrolled medical condition that precludes surgical management
- Must not have active infection that precludes enrollment
- HIV-infected patients on effective anti-retroviral therapy with undetectable viral load ≤ 6 months prior to randomization are eligible
- Must not have a prior or concurrent malignancy whose natural history or treatment has the potential to interfere with safety or efficacy assessment of this trial
- Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, must be NYHA Functional Classification class 2B or better
- Must be English-speaking

Note: Co-enrollment is permitted on a case-by-case basis

Treatment Plan

See protocol Section 5 for complete treatment details

- Patients must complete PROs after consent and prior to randomization
- If a patient undergoes complete lymph node dissection after a positive sentinel lymph node biopsy, they are considered unevaluable. If a patient subsequently undergoes therapeutic (complete) lymph node dissection at nodal basin recurrence, they will remain on study for long-term follow up
- Assigned surgical intervention must occur ≤ 45 days after randomization
  - ◊ Delays due to unforeseen illness or hospitalization must not exceed additional 21 days

Arm A: Standard of Care

- WLE and SLN biopsy
- Nodal basin surveillance for patients who are node-positive, utilizing US or CT per institutional/physician preference
  - ◊ If node-negative, surveillance may be done per physician preference

Arm B: De-escalated Arm

- WLE only
- Nodal basin surveillance (modality per physician preference)

Adjuvant Therapy (Arms A & B)

- After surgery, patients may receive any adjuvant therapy, if clinically indicated, per physician discretion
  - ◊ Includes SOC and investigational regimens
- Dose interruptions, delays, and discontinuation of adjuvant therapy regimen are allowed and will follow institutional guidelines

Study Chair:
Yana Najjar, MD

Study Co-Chair:
Rino Seedor, MD

NCTN Study Champions:

- ***Alliance:*** Danielle Bello, MD
- ***SWOG:*** Vincent Ma, MD

Patient Enrollment (Oncology Patient Enrollment Network [OPEN])

https://open.ctsu.org/open

1-888-823-5923

Protocol Information (ECOG-ACRIN Operations – Boston)

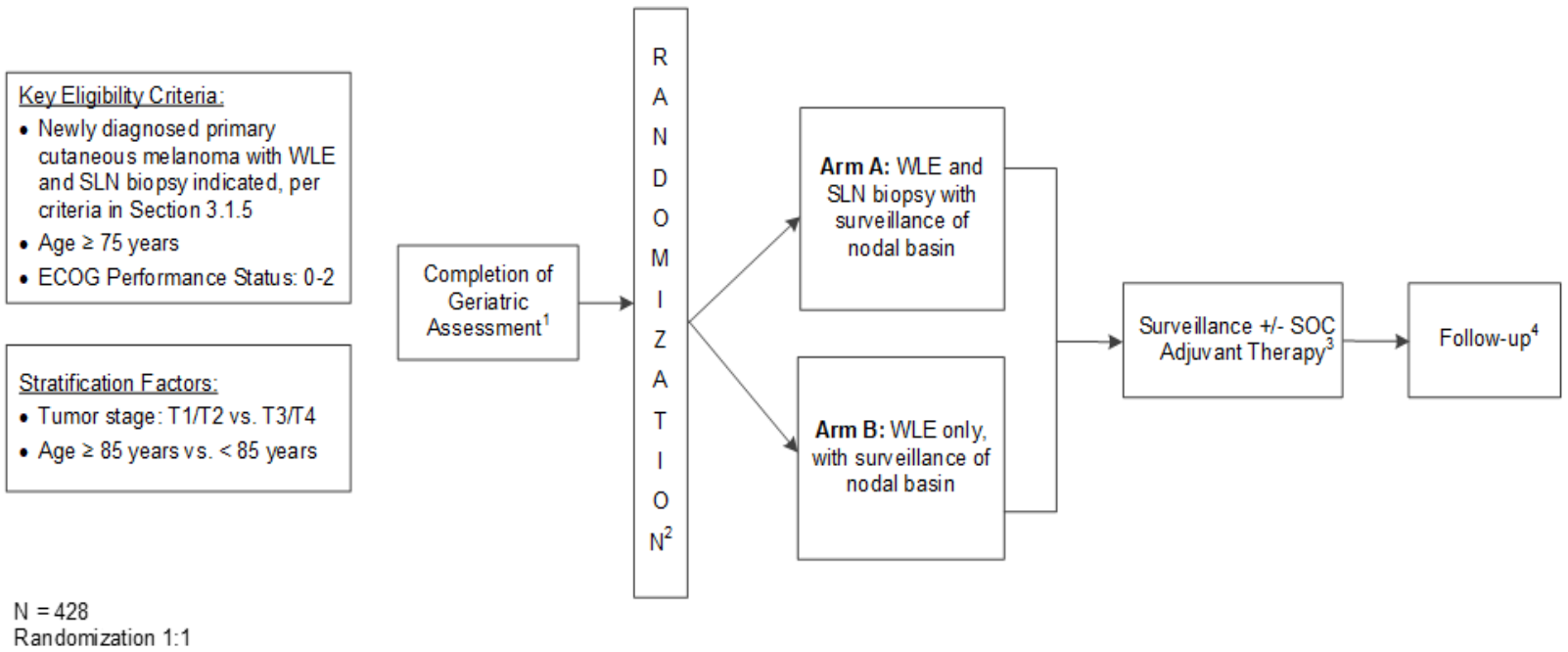
http://ecog-acrin.org (Member Login)

1-857-504-2900

v.03/03/26

EA6244

Schema



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.