

NCI

Community  
Oncology  
Research  
Program

# EA6232

ECOG-ACRIN  
cancer research group

**Please Enroll  
Your Eligible  
Patients!**

## Prevention for Melanoma Patients with Atypical Nevi

### EA6232 Available Through ECOG-ACRIN Cancer Research Group

A Phase II Double-Blind Trial of Sulforaphane for Therapeutic Prevention of Melanoma in Patients with Multiple Atypical Nevi and a Prior History of Melanoma

#### Patient Population

See protocol Section 3 for complete eligibility criteria

- Must be  $\geq 18$  years of age
- Must not be pregnant
- Must have  $\geq 3$  clinically atypical nevi, assessed within 30 days prior to randomization, that are consistent with the International Agency for Research on Cancer (IARC) definition:
  - ◇ Must have a diameter of  $\geq 5$  mm in one dimension
  - ◇ Must include a macular component in at least one area
  - ◇ Must have at least 2 of the following features: ill-defined borders, color variegation, uneven contour, and erythema
  - ◇ Note: lesions suspicious for incipient melanoma will be removed and are not intended for EA6232
- Must have a prior diagnosis of early-stage melanoma, defined as either melanoma in-situ, localized resected stage I-II node negative melanoma, or resected node positive stage III melanoma who in the assessment of their physician have a low risk of relapse of their prior melanoma within 1 year of randomization
- Must not be currently on targeted or checkpoint immunotherapy or treated within 365 days prior to randomization
- HIV, HBV, and HCV- infected patients are permitted per protocol
- Patients with a prior/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
- Must not have a known allergy to cruciferous vegetables
- Must not use any other sulforaphane-containing dietary supplement during the study period
- Must not be on any current systemic treatment for melanoma

#### Treatment Plan

See protocol section 5 for complete treatment details

- Patients will be randomized to receive either sulforaphane or placebo for 12 months
  - ◇ **Arm A:** Sulforaphane- 3 tablets of Avmacol Extra Strength (Nutramax) by mouth, once daily; swallow tablets whole with a full glass of water and take with a meal to reduce any gastrointestinal side effects
  - ◇ **Arm B:** Placebo- 3 tablets by mouth, once daily
- Treatment must start within 10 calendar days (including holidays) after randomization
- Sulforaphane infrequently may cause nausea, vomiting or GI discomfort; refer to Section 5.3 for allowable dose reductions according to adverse events
  - ◇ The maximum dose delay allowed on the protocol for any reason is 21 days
- Patients are required to complete medication calendars while receiving study treatment, which should be returned and reviewed at each clinic visit (see Appendix IV)
- Patients will be followed for response until progression and for survival every 3 months for 24 months from randomization
  - ◇ See Section 6 for photographic response assessment requirements

**Study Chair:**  
John M. Kirkwood, MD

### Patient Enrollment (Oncology Patient Enrollment Network [OPEN])



<https://open.ctsu.org/open>



1-888-823-5923

### Protocol Information (ECOG-ACRIN Operations – Boston)



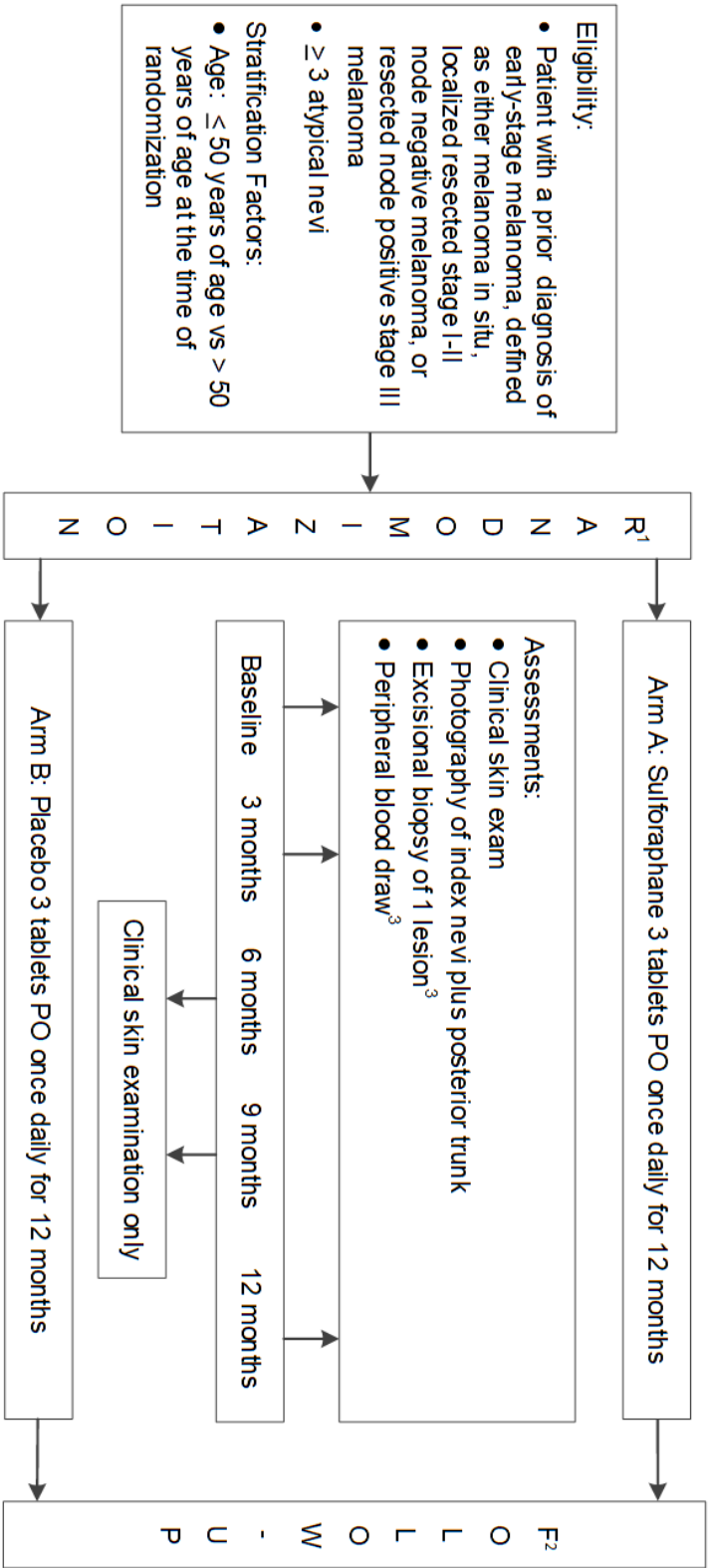
<http://ecog-acrin.org> (Member Login)



1-857-504-2900

# EA6232

## Schema



Accrual = 120 patients

1. Please note that when a patient has been successfully randomized, the confirmation of randomization will indicate that the patient is on Arm X. This reflects that the patient has been randomized to Arm A or B, but as this is a double-blind trial, that information cannot be displayed.
2. Patients will be followed for response for 24 months from the date of randomization.
3. Optional submission per patient consent.