NCI Community Oncology Research Program

EA9131

ECOG-ACRIN cancer research group
Reshaping the future of patient care

For Patients with Acute Promyelocytic Leukemia

EA9131 Available Through ECOG-ACRIN Cancer Research Group

A Simplified Patient Care Strategy to Decrease Early Deaths in Acute Promyelocytic Leukemia (APL)

Patient Population

See Section 3.0 for Complete Eligibility Details

- All patients ≥ 18 years of age who are confirmed to have a diagnosis of APL, which is defined as:
  - ◊ Positive t(15;17) by FISH or conventional karyotype
  - ◊ Positive PML/RAR alpha by PCR
- Must accept treatment and supportive care guidelines
- Referrals must be made as early as possible by treating physician (provider) but no later than 3 calendar days after ATRA or APL directed therapy is initiated
  - ◊ Consent can be obtained up until day 7 or earlier
- Co-management can be started as soon as referral is made including weekends. The physician at the NCORP community facility should make every effort to call the APL expert at the first suspicion of APL

One NCORP site and five NCTN Sites will be referred to as the Lead Sites: Medical College of Georgia at Augusta University, Augusta, GA; Memorial Sloan Kettering Cancer Center, New York, NY; Mayo Clinic, Rochester, MN; Northwestern University, Chicago, IL; University of Pennsylvania, Philadelphia, PA and Mayo Clinic, Jacksonville, FL

NOTE: Other Academic sites will not participate in this trial. EA9131 will be restricted to the above-mentioned FIVE NCTN SITES and ALL NCORP COMMUNITY SITES

Treatment Plan

See Section 5.0 for Complete Methodology Details

Lead Sites:

- 7 lead investigators accruing at 6 lead sites (Lead Sites) will serve as the APL experts
  - ◊ The APL expert will either manage the patient or provide consultative oversight to the treating team
  - ◊ The sub-investigators at the lead sites can consent patients but it is expected that the local PI will provide oversight
- Patients treated at lead sites will be treated locally using treatment guidelines (Appendix I)

Outlying NCORP Community Facilities:

- The treating physician from the NCORP community facility should call the APL expert in their catchment area for treatment guidance
  - ◊ The call should be made as soon as APL is suspected but no later than 3 days after starting ATRA; communication should be ongoing based on the clinical developments until a hematologic remission is achieved
  - ◊ The provider at NCORP community centers will be the Hematologist/Oncologist attending caring for the patient; initial contact has to be made by a hematologist/oncologist, but trainees or advanced level practice providers can be in communication subsequently with APL experts to continue the care
- A log will be maintained by the APL expert (Appendix II); subsequent calls/decisions made will be documented on the log sheet; it is also suggested that the treating physician document communication on an ongoing basis
- Study duration is 5 years: Accrual years 1—4 and follow-up for1 year after accrual is completed

Study Chair:
Anand P. Jillella, M.D.

Co-Chair:
Vamsi K. Kota, M. D.

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

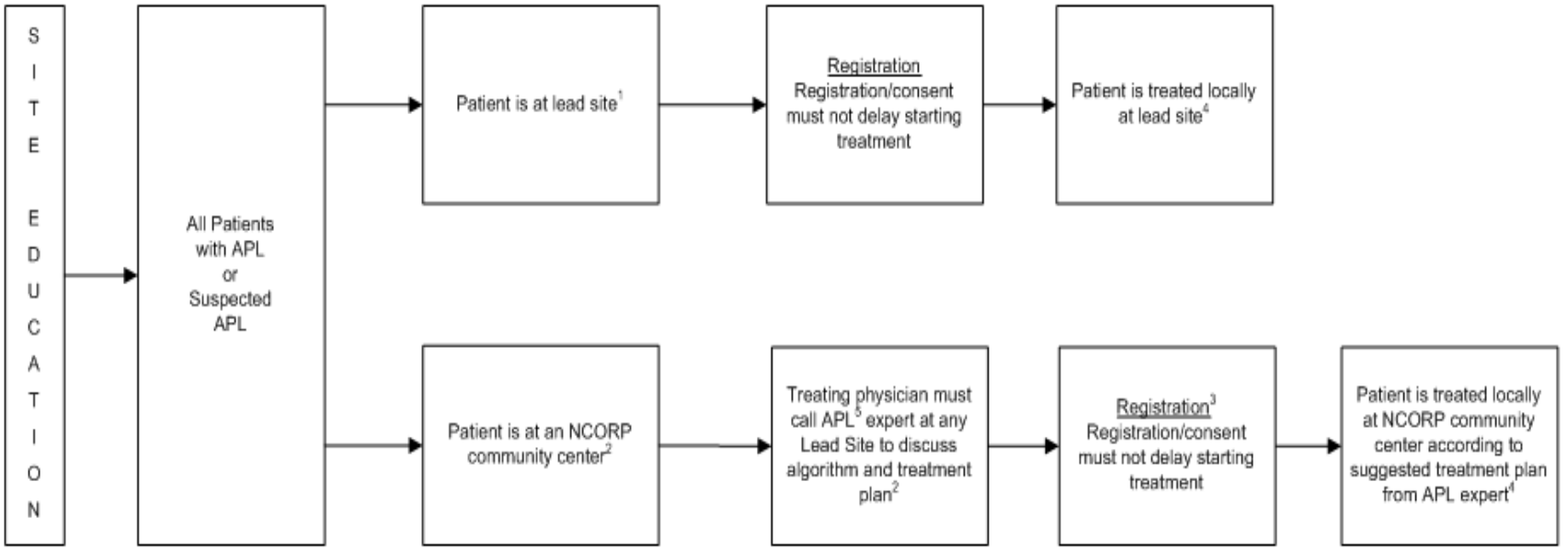
Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

EA9131

Schema



Total Accrual Goal= 200

1. Participation at lead sites will be limited to 30% of overall accrual. Lead sites are identified as: Medical College of George at Augusta University, MSKCC, Mayo Clinic - Rochester, MN, Northwestern, University of Pennsylvania, Mayo Clinic - Jacksonville, FL.
2. It is preferred the APL expert for the catchment area is contacted first. It is suggested that the call be placed as soon as a diagnosis is suspected.
3. Registration is done only if treating physician calls expert within 3 days of starting APL directed treatment.
4. Follow treatment guidelines according to Appendix I. If necessary, deviations from guidelines may occur per discretion of treating physician and consulting physician.
5. 7 investigators at the lead sites have been identified as APL experts.