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

**Overall EA9131 Study Objective**

To examine whether co-managing patients by discussions between acute promyelocytic leukemia (APL) experts and treating physicians in combination with following modified treatment guidelines can ensure better adherence to guidelines and earlier recognition of impending complications to thereby improve survival.

**Accrual goal = 200 patients.**

The trial will be conducted at NCORP community and select lead sites.

1. Lead sites are identified as: Medical College of Georgia at Augusta University, Memorial Sloan Kettering Cancer Center, Mayo Clinic-Rochester, MN, Northwestern, University of Pennsylvania, and Mayo Clinic-Jacksonville, FL. Participation at the 6 lead NCTN sites will be limited to 30% of accrual.
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 diagnosis is suspected.
3. Consent patient after APL diagnosis is confirmed.
4. 7 investigators at the lead sites have been identified as APL experts.
5. Follow treatment guidelines according to Appendix I. If necessary, deviations from guidelines may occur per discretion of treating and consulting physicians.
6. Registration is done only if treating physician calls expert within 3 days of starting treatment.

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**Study Schema**

- All patients with APL or Suspected APL
- Patient is at a lead site
- Registration
  - Registration/consent must not delay starting treatment
  - Patient is treated locally at lead site
- Patient is at an NCORP community center
- Treating physician must call APL expert at any lead site to discuss algorithm and treatment plan
- Registration
  - Registration/consent must not delay starting treatment
  - Patient is treated locally at NCORP community center according to suggested treatment plan from APL expert

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Registeration/consent must not delay starting treatment.
**Study Objectives**

**Primary Objective**
- Evaluate if the proposed patient care strategy, which includes use of simplified guidelines along with APL expert support, decreases the 1-month induction mortality rate from 30% to under 15%

**Secondary Objectives**
- Assess overall survival 1 year after accrual is completed
- Assess incidence and severity of differentiation syndrome
- Correlate outcomes with time to initiation of all-trans retinoic acid (ATRA) from diagnosis or suspicion of diagnosis
- Evaluate outcomes in academic and community centers separately
- Evaluate factors associated with outcome

**Eligibility Criteria***
- ≥ 18 years of age with confirmed diagnosis of APL, defined as
  - Positive t(15:17) by FISH or conventional karyotype OR positive promyelocytic leukemia/retinoic acid receptor (PML/RAR) alpha by polymerase chain reaction (PCR)
- Patients 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 until day 7 after initiating APL directed therapy.
- Co-management can be started as soon as referral is made, including on weekends. The physician at the NCORP community facility should make every effort to call the APL expert at first suspicion of APL

*When evaluating patients for this study, please refer to the full protocol for the complete list of eligibility criteria.