Cancer Research Consortium of West Michigan
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FAST FACTS

ALLIANCE A041701
A RANDOMIZED PHASE II/III STUDY OF CONVENTIONAL CHEMOTHERAPY +/- UPROLESELAN (GMI- 1271) IN OLDER ADULTS WITH ACUTE MYELOID LEUKEMIA RECEIVING INTENSIVE INDUCTION CHEMOTHERAPY

Registration Eligibility Criteria (Step 1)

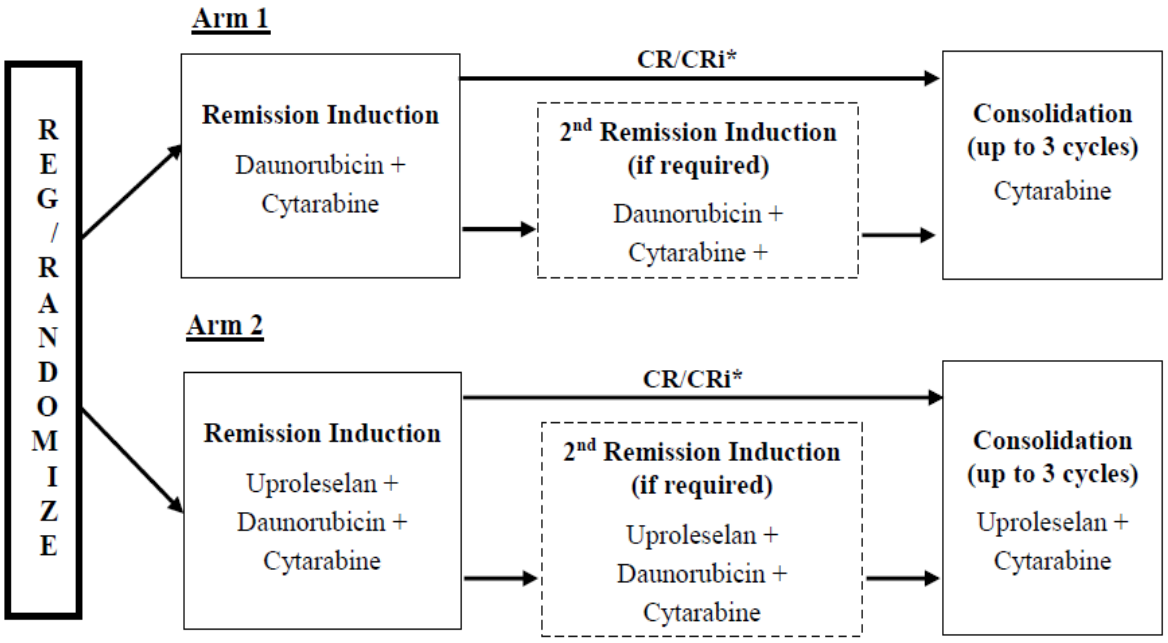
1. Documentation of Disease
- Diagnosis of AML based on 2017 WHO criteria [22] excluding acute promyelocytic leukemia with PML-RARA. Note: Patients with myeloid sarcoma without bone marrow involvement, acute leukemia of ambiguous lineage or blast transformation of CML are not eligible.
- No activating mutation in the Fms-like tyrosine kinase-3 (FLT3) defined as a ratio of mutant to wild-type allele ≥ 0.05 by capillary electrophoresis or a variant allele fraction of ≥ 5% by next generation sequencing from either bone marrow or peripheral blood.
- No evidence of CNS involvement of AML

2. Prior Treatment
- No prior chemotherapy for MDS or AML including hypomethylating agents (e.g. azacitidine and decitabine) or lenalidomide with the following exceptions:
  - Emergency leukapheresis
  - Hydroxyurea
  - Growth factor/cytokine support
  - All-trans retinoic acid (ATRA)
  - Single dose of intrathecal cytarabine and/or methotrexate for patients undergoing lumbar puncture to evaluate for CNS involvement

3. Age ≥ 60 years

4. Required Initial Laboratory Values
- Total Bilirubin ≤ 3 x upper limit of normal (ULN)
- Creatinine ≤ 3 x upper limit of normal (ULN)
  OR
- Creatinine Clearance ≥ 30 mL/min/1.73m^2

Schema



* During Remission Induction, a bone marrow examination (aspirate and biopsy) on Day 14 (+3 days) is required in all patients. Patients with evidence of persistent leukemia on day 14 or a subsequent bone marrow biopsy will receive a second induction course (See Section 7.0). Patients who achieve either a CR or CRi are eligible to proceed to consolidation therapy.