

S0106

For Patients Under Age 61 With Previously Untreated De Novo Acute Myeloid Leukemia

S0106 Available Through the CTSU

A Phase III Study of the Addition of Gemtuzumab Ozogamicin (Mylotarg®) Induction Therapy Versus Standard Induction With Daunomycin and Cytosine Arabinoside Followed by Consolidation and Subsequent Randomization to Post-Consolidation Therapy With Gemtuzumab Ozogamicin (Mylotarg®) or No Additional Therapy for Patients Under Age 61 With Previously Untreated De Novo Acute Myeloid Leukemia (AML)

Patient Population

See Section 5.0 for Complete Eligibility Details

- Morphologically confirmed diagnosis of AML with FAB classification other than M3, based on bone marrow aspiration & biopsy performed 14 days prior to registration (see Section 5.1.a)
- Age ≥ 18 , < 61 ,
- Zubrod performance status 0-3
- Patients must not have received systemic chemotherapy or more than one dose of intrathecal chemotherapy for acute leukemia. Prior hydroxyurea is allowed.
- SWOG patients must be registered on SWOG-9007 and S9910 (see Sections 5.1.h-i).
- No pregnancy or breastfeeding; patients must be willing to use contraception if applicable.
- No other prior malignancy is allowed except for those specified in section 5.1.i.
- No known liver disease or hepatitis B (HbsAg +) or hepatitis C
- **Number of Participants: 684**

Treatment Plan

Induction (Randomized):

Arm 1

Daunomycin 45mg/m² IVP Days 1-3
Ara-C 100mg/m²/day CIVI Days 1-7
Gemtuzumab ozogamicin 6mg/m² IV Day 4
Growth factor per protocol

Arm 2

Daunomycin 60mg/m² IVP Days 1-3
Ara-C 100mg/m²/day CIVI Days 1-7
Growth factor per protocol

If necessary, a second induction course (without gemtuzumab orzogamicin) will be given (per Section 7.2).

Consolidation (Additional eligibility):

Ara-C 3gm/m² q12 hours IV Days 1, 3, 5 x 3 28-day cycles

Post-Consolidation (Additional eligibility and randomization):

ARM 1:

Gemtuzumab ozogamicin 5mg/m² IV x 3 doses at least 28 hours apart

ARM 2:

No therapy

Patient Enrollment

Non-SWOG Members: CTSU Patient Registrar 1-888-462-3009

Protocol Information

CTSU Help Desk 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

SWOG

Protocol Chair:

Stephen Petersdorf, MD
David Head, MD

NCIC-CTG

Co-Chair:

Tom Neville, MD

Schema

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SCHEMA

