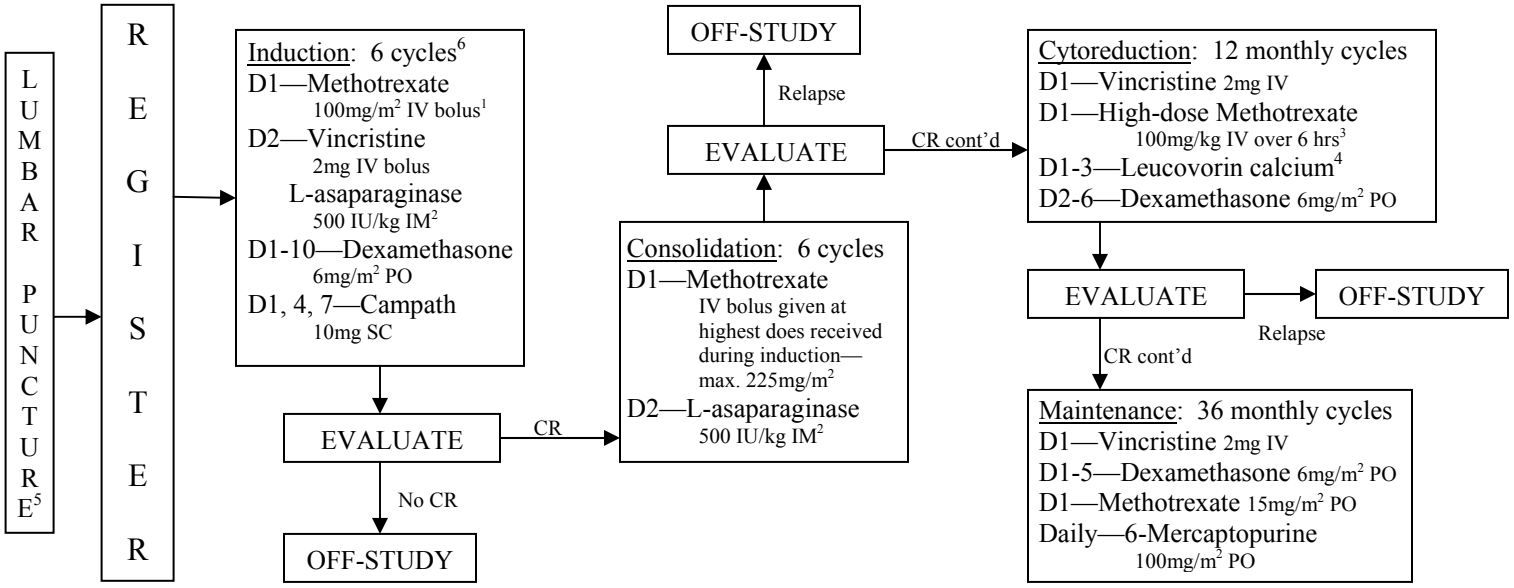
E1904: A Phase II Study of MOAD (Methotrexate, Vincristine, L-asparaginase, and Dexamethasone) with Subcutaneous Campath for Adults with Relapsed or Refractory Acute Lymphocytic Leukemia (ALL)



[1] Escalate methotrexate dose by 50% per cycle up to 225mg/m² during Induction and by 25% during Consolidation
[2] If allergy to E. coli asparaginase develops, complete therapy with Leucovorin calcium
[3] Increase each subsequent dose by 25% until minimal toxicity. NOTE for high-dose methotrexate it is 100mg/kg *not* mg/m²
[4] Leucovorin calcium is a continuous 3-day infusion; dose = 5% high dose methotrexate given; 3rd day dose given orally in 4 doses
[5] If the lumbar puncture is positive, patient receives intrathecal methotrexate, 15mg QOD until 2 successive lumbar punctures, 3 days apart, are free of leukemic cells; 2 additional QOD does are given, then one 15mg dose every 30 days for 6 doses; preservative-free methotrexate should be used for intrathecal injection
[6] 1 cycle = 10 days

MAJOR ELIGIBILITY CRITERIA:

- Must be in first relapse of ALL or failed to achieve CR with a prior regimen.
- Age ≥18 with an ECOG performance status of 0-3.
- Patients with a history of CNS leukemia must have a normal cerebrospinal fluid at time of enrollment.
- Must not be infected with bacteria or fungi, or must have such an infection under treatment and responding to appropriate antibiotics.
- Must have no other malignancy diagnosed within 5 years of study entry, except basal cell carcinoma of skin or cervical carcinoma for which successful treatment has been given.
- Patients of childbearing potential must agree to use adequate contraception prior to study entry. Women must not be pregnant or breastfeeding.
- Must have hepatic and renal function within ULN within 1 week of protocol entry. Bilirubin and creatinine must be no higher than ULN prior to each parenteral dose of methotrexate.
- Must not be HIV+, hepatitis B+, or have evidence of active CMV infection by molecular detection methods.

PATIENTS NEED TO ALSO BE ENTERED ON E3903

PRE-STUDY LABS AND TESTS:

≤ 4 weeks prior to registration:	Chest X-ray, EKG
≤ 2 weeks prior to registration:	Pregnancy test, if applicable
≤ 1 week prior to registration:	CBC with diff., platelets, creatinine, uric acid, BUN, total bili., AST, ALT, LDH, Alk. Phos., CMV monitoring, HIV test, lumbar puncture, bone marrow biopsy and aspiration, creatinine clearance

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