

**Intensified Methotrexate, Nelarabine (Compound 506U78; IND # 52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-cell Acute Lymphoblastic Leukemia (AALL0434)**

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**Synopsis:**

This study is to determine the relative safety and efficacy of high dose methotrexate (5gm/m<sup>2</sup>) with leucovorin rescue compared to escalating methotrexate without leucovorin rescue plus PEG-Asparaginase (Capizzi I) delivered during Interim Maintenance. The secondary clinical objective is to determine the relative safety and efficacy of withholding radiation in patients with low risk T-ALL, while treating intermediate and high-risk patients with 1200 cGy of prophylactic cranial radiation.

All patients will receive the same Induction treatment. Patients will be assigned a risk status and randomized to Part II treatment as described above.

After safety has been determined in the safety phase of the study, the efficacy phase randomization process will begin.

Treatment, except for use of nelarabine, is standard of care. Nelarabine is used in the safety phase only in high risk patients and in the efficacy phase in intermediate and high risk patients.

*Arm A:*

Randomization → low dose MTX, Consolidation (with radiation to the brain), → Interim Maintenance with low dose MTX, → Delayed Intensification, → Maintenance

*Arm B:*

Randomization → low dose MTX, Consolidation + nelarabine (with radiation to the brain), → Interim Maintenance with low dose MTX, → Delayed Intensification, → Maintenance

*Arm C:*

Randomization → high dose MTX, Consolidation → Interim Maintenance with high dose MTX, → Delayed Intensification (with radiation to the brain), → Maintenance

*Arm D:*

Randomization → high dose MTX, Consolidation + nelarabine → Interim Maintenance with high dose MTX, → Delayed Intensification (with radiation to the brain), → Maintenance