Title: COG AALL06N1: A Study of Neurocognitive Function in Children Treated for ALL.

Purpose: To determine the effects, if any, of methotrexate, on learning skills and memory. Will also determine whether rare, sudden side effects of leukemia therapy, such as seizures, are associated with learning difficulties; whether certain genetic traits (qualities of DNA that make someone unique) are associated with the possibility of methotrexate side effects; whether changes in the amounts of a substance that is found in the body are associated with side effects of methotrexate, and whether or not a new imaging study, similar to an MRI, will predict who is at risk for side effects related to methotrexate.

Eligibility: Patient must be at least 1 year old and less than 18 years of age. Patient must be enrolled on AALL0434 or AALL0232. Patient must NOT have any of the following: 1) Presence of a known significant neurodevelopmental disability unrelated to the cancer diagnosis (e.g., Down Syndrome, Fragile X mental retardation, autism, pervasive developmental disability, pre-existing seizure disorder). Children with a prior history of attention deficit hyperactivity disorder or a specific learning disability (e.g., dyslexia) is eligible for this study. 2) Sensory impairment (e.g., pre-existing uncorrectable vision impairment or deafness). 3) CNS-3 disease at diagnosis nor be scheduled to receive cranial radiation therapy (CRT).

Principal Investigator: Wiley, Joseph M.

Phase: III

For more information, contact: Entrup, Stephanie

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Approved Enrollment Number: 5

Current Enrollment: 0
Title: COG AALL1122 (BMS CA180-372): A Phase 2 Multi-Center Historically-Controlled Study of Dasatinib Added to Standard Chemotherapy in Pediatric Patients with Newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia.

Purpose: To find out what the survival rate is when dasatinib is added to a standard chemotherapy. Additional goals of the study are to evaluate the side effects of dasatinib added to standard chemotherapy, to compare the survival rate in this study to that seen with a similar but less potent drug called imatinib when added to this same chemotherapy and other treatments and to monitor the response of your disease to this treatment with disease specific tests (minimal residual disease).

Eligibility: Males and females, age > 1 year (365 days) and < 18 (17 years and 364 days) years at diagnosis. Must have Philadelphia chromosome-positive acute lymphoblastic leukemia.

Principal Investigator: Wiley, Joseph M.

Phase: II

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Approved Enrollment Number: 5

Current Enrollment: 0
Title: COG AALL1131: A Phase III Randomized Trial for Newly Diagnosed High Risk B-precursor Acute Lymphoblastic Leukemia (ALL) Testing Clofarabine (IND# 73789, NSVC# 606869) in the Very High Risk Stratum: A Groupwide Phase III Study.

Purpose: To determine if the administration of post-Induction age adjusted ITT on an MBFM-IMHDM backbone will improve 5-year DFS of children with HR-ALL compared to age adjusted IT MTX. To determine, in a randomized fashion, if the cyclophosphamide + etoposide containing regimen (Experimental Arm 1) or the clofarabine + cyclophosphamide + etoposide combination regimen (Experimental Arm 2) will improve the 4-year DFS of children, adolescents, and young adults with VHR-ALL compared to a modified MBFM-IMHDM regimen that contains a second IM (Control Arm). To determine, in a randomized fashion, if the cyclophosphamide + etoposide + clofarabine containing combination regimen (Experimental Arm 2) will improve the 4-year DFS of children, adolescents, and young adults with VHR-ALL compared to the cyclophosphamide + etoposide combination regimen (Experimental Arm 1).

Eligibility: Have NCI High risk all or NCI standard risk all with central nervous system (CNS), Testicular Leukemia, and/or steroid pre-treatment and be enrolled in COG AALL08B1. Patients that begin protocol therapy on this study (AALL1131) prior to enrollment on AALL08B1 are ineligible; or have NCI standard risk all, be enrolled in COG AALL08B1 and COG AALL0932 and completed AALL0932 induction treatment and been classified as high risk or very high risk.

Principal Investigator: Wiley, Joseph M.

Phase: III

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Approved Enrollment Number: 

Current Enrollment: 0
**Title:** Intensified Methotrexate, Compound 506U78 (Nelarabine: IND #52611) and Augmented BFM Therapy for Children and Young Adults with Newly Diagnosed T-cell Acute Lymphoblastic Leukemia. (COG AALL0434)

**Purpose:** To determine, through randomization, the relative safety and efficacy of the addition of Nelarabine (Compound 506U78) to augmented BFM therapy (Regimen C, CCG-1961). To determine the relative safety and efficacy of high dose methotrexate (5gm/m2) with leucovorin rescue compared to escalating methotrexate without leucovorin rescue plus PEG-Asparaginase (Capizzi I) delivered during Interim Maintenance.

**Eligibility:** T-ALL patients must be enrolled on AALL03B1/AALL0-8B1 prior to treatment and enrollment on this study. Patients must be greater than 1 and less than 31 years of age. Patient must have newly diagnosed T-cell acute lymphoblastic (T-ALL) or T-lineage lymphoblastic lymphoma (T-NHL) Stage II-IV. B-lineage lymphoblastic lymphoma will not be eligible for this study. Patients shall have had no prior cytotoxic chemotherapy with the exception of steroids and/or IT cytarabine. Patients with a prior seizure disorder requiring anti-convulsant therapy are not eligible to receive Nelarabine. In addition, patients with pre-existing Grade 2 (or greater) peripheral neurotoxicity, as determined prior to Induction treatment by the treating physician or a neurologist, are not eligible to receive Nelarabine. Patients with Down Syndrome are ineligible to enroll onto this study.

**Principal Investigator:** Wiley, Joseph M.

**Phase:** III

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**Approved Enrollment Number:** 5

**Current Enrollment:** 4
Title: Intensive Treatment for Intermediate-Risk Relapse of Childhood B-Precursor Acute Lymphoblastic Leukemia (ALL): A Randomized Trial of Vincristine Strategies. (COG AALL0433)

Purpose: To establish the efficacy of an intensive chemotherapy regimen (based on POG 9412) for patients with intermediate-risk relapse of childhood B-precursor ALL (defined as late marrow/combined relapse greater than or equal to 36 months from diagnosis or early isolated CNS/testicular relapse less than 18 months from diagnosis.

Eligibility: Patients between 1 year and 29.99 years of age (inclusive) at the time of relapse will be eligible. Patient with an initial intermediate-risk relapse of B-precursor Acute Lymphoblastic Leukemia (ALL) will be eligible.

Principal Investigator: Wiley, Joseph M.

Phase: III

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Approved Enrollment Number: 5

Current Enrollment: 0
Title: COG AALL0631: A Phase III Study of Risk Directed Therapy for Infants with Acute Lymphoblastic Leukemia (ALL): Randomization of Highest Risk Infants to Intensive Chemotherapy +/- FLT3 Inhibition (CEP-701, Lestaurtinib: IND #76431; NSC #617807)

Purpose: To compare the 3-year event-free survival (EFS) of infants with MLL-R ALL randomized to treatment with a modified P9407 chemotherapy backbone with or without the FLT3 inhibitor lestaurtinib. To determine a safe, tolerable and biologically additive dose of lestaurtinib given in sequential combination with chemotherapy in MLL-R infants. To characterize the pharmacokinetics and pharmacodynamics of lestaurtinib in infants when given at the proposed dose in sequential combination with chemotherapy. To identify molecular mechanisms of resistance to lestaurtinib in leukemic blasts. To describe levels of minimal residual disease in infants with ALL within the context of the proposed therapy, and correlate with outcome. To identify gene expression patterns in diagnostic infant leukemia samples that correlate with outcome within the context of the proposed therapy. To describe the outcome of infants with MLL-G ALL treated with a modified P9407 chemotherapy backbone that includes an extended Continuation phase.

Eligibility: Infants who have been diagnosed with Acute Lymphoblastic Leukemia (ALL)

Principal Investigator: Wiley, Joseph M.

Phase: III

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Approved Enrollment Number: 5

Current Enrollment: 1
Title: COG AALL0932: Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia (ALL)


Eligibility: Patients greater than one year of age and less than ten years of age with newly diagnosed ALL and must participate in COG AALL08B1 prior to participation in AALL0932 in order to accurately classify as Standard Risk.

Principal Investigator: Wiley, Joseph M.

Phase: III

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Approved Enrollment Number: 25

Current Enrollment: 6