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Abstract

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Grant Number: 5R01NR007610-02

PI Name: HINDS, PAMELA SUE.

PI Title: DIRECTOR OF NURSING RESEARCH

Project Title: SLEEP, FATIGUE, AND DEXAMETHOSONE IN CHILDHOOD CANCER

Abstract: *Mounting evidence indicates that adding dexamethasone to the therapy for children and adolescents diagnosed with lymphoblastic leukernia contributes to more positive long-term outcomes such as lower rates of meningeal leukemia. The significant positive contributions of dexamethasone have not occurred without adverse effects including avascular necrosis. mania and psychosis, and aberrant sleep and fatigue. These adverse effects could be related to inter-individual variability in the systemic exposure to dexamethasone and if so, the adverse effects could serve as behavioral indicators of patient sensitivity to the dosing schedule. To determine whether dexamethasone dosing schedules need to be individualized to minimize adverse effects while maintaining antileukernic effects, the relationship between inter-individual variability and adverse effects must be established. The overall purpose of this two-site study is to determine the relationship between systemic exposure to dexamethasone and patients' sleep and fatigue by comparing multiple indicators of patient sleep and fatigue in two consecutive 5-day periods during Continuation therapy off and on dexatnethasone. Approximately 134 children and adolescents with low or standard fisk ALL will wear a wnist actigraph for the two consecutive 5-day study periods and will complete a self-report fatigue questionnaire during a telephone interview on Days 2 and 5 of both study periods. Their parents will complete a sleep diary and a fatigue questionnaire on Days 2 and 5 of both study periods regarding their child's sleep and fatigue patterns. In addition, on Day I of the on dexamethasone 5-day study period, patients will-have sequential blood samples collected pre- and post- the morning dose of dexamethasone. These samples will be analyzed for dexamethasone pharmacokinetics and genetic polymorphism. Using these data, we will*

test the hypothesis that dexamethasone contributes to aberrant sleep and increased fatigue in children and adolescents with ALL, and that the altered sleep and fatigue are related to the pharmacokinetics of the drug. Our study findings will explicate the relationship between sleep efficiency and fatigue, and between sleep, fatigue, and systemic exposure to dexamethasone.

Thesaurus Terms:
acute lymphocytic leukemia, dexamethasone, drug adverse effect, fatigue, neoplasm /cancer chemotherapy, pediatric neoplasm /cancer, pharmacokinetics, sleep disorder adolescence (12-18), age difference, dosage, drug administration rate /duration, drug screening /evaluation, gender difference, genetic polymorphism, human therapy evaluation, middle childhood (6-11), pharmacogenetics
blood chemistry, clinical research, human subject, patient monitoring device, personal log /diary, preschool child (1-5), questionnaire

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