

CLINICAL TRIAL SUMMARY DESCRIPTION

TRIAL INFORMATION:

Is this a CLINICAL TRIAL or a RESEARCH STUDY ?

Is this a NEW Submission or an UPDATE of one already submitted?

TITLE: Early Identification of Cognitive Deficits in Children with Neurofibromatosis Type 1

PHASE: 1

DRUG/TREATMENT: No drug treatment, only a neuropsychological assessment

OBJECTIVE OF STUDY: The purpose of this study is to characterize the neurocognitive development of children with NF1 from 5 months to 7 years of age by neuropsychological/ developmental assessment to identify early predictors of cognitive outcome in young children with NF1. We will also look at the onset of MRI-T2 hyperintensities on MRI scan.

LOCATIONS: Children's National Medical Center
111 Michigan Avenue NW, Washington, DC 20010

TRIAL WEBSITE: we do not have one

MINIMUM ELIGIBILITY REQUIREMENTS:

AGE/GENDER REQUIREMENTS: We are looking for participants for part 1 and part 2.

For part 1 participants must be between the ages 5 years –16 years

For part 2 participants must be between the ages of 5months-40 months

OTHER REQUIREMENTS:

Inclusion Criteria:

- All participants must meet NIH NF1 diagnostic criteria at the time of enrollment. (Appendix C)
- Any child with NF1 who is 40 months of age or younger at the time of enrollment.

Exclusion Criteria:

- Children who do not meet NIH NF1 diagnostic criteria. (Appendix X)
- Children older than 40 months of age.
- Children with intracranial pathology such as brain tumors, epilepsy or hydrocephalus.
- Children with significant hearing or visual problems.

RECRUITMENT START DATE: September 1, 2005

TRIAL CONTACT FOR INTERESTED PARTICIPANTS:

NAME/TITLE: Maria Acosta, MD and Leah Seldin-Sommer, BA (study coordinator)

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