

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: Phase I study of Lovastatin for Neurocognitive Dysfunction in Children with Neurofibromatosis Type 1

PHASE: 1

DRUG/TREATMENT: lovastatin

OBJECTIVE OF STUDY: The main goal of the present study is to evaluate the use of Lovastatin to improve cognitive deficits in NF1 patients.

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

TRIAL WEBSITE: do not have one

MINIMUM ELIGIBILITY REQUIREMENTS:

AGE/GENDER REQUIREMENTS: 10-17 years old

OTHER REQUIREMENTS:

Inclusion Criteria:

- Males or females aged 10 to 17
- Participants must be diagnosed with neurofibromatosis Type 1
- Participants must be diagnosed with learning disabilities before entrance into the study
- Participants must have not history of medical conditions other than NF Type 1

Exclusion Criteria

- Participants with a full scale IQ less than 80 will be excluded from the study.
- Individuals who do not speak English as a first language.
- Significant medical conditions other than NF Type 1

RECRUITMENT START DATE: January 1, 2006

TRIAL CONTACT FOR INTERESTED PARTICIPANTS:

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

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