



Kennedy Krieger Institute

*A comprehensive resource for
children with disabilities*

Down Syndrome Clinic
801 North Broadway
Baltimore MD, 21205

December 21, 2009

Dear parents, colleagues, and friends,

I am writing to invite you to participate in a research study we are undertaking with collaborators at Duke University: a clinical trial of rivastigmine in children with Down syndrome. Rivastigmine is FDA-approved for managing symptoms associated with Alzheimer's Disease. A small open-label 20-week study of rivastigmine in children with DS (published in *Journal of Child and Adolescent Psychopharmacology*) found improvements in overall adaptive function, attention, memory, and language. Results of that study suggest the need for a larger controlled study of the same nature.

Please look at the enclosed flyer with details on the study and consider sharing the information with families who might be eligible to participate. Those who are interested may contact Marie Andachter, Research Coordinator, for more information (443-923-7716 or andachter@kennedykrieger.org).

Sincere thanks,

George T. Capone, MD
Principal Investigator
Director, Down Syndrome Clinic

Marie Andachter
Research Coordinator
443-923-7716
andachter@kennedykrieger.org



Approved 04/10/2008

Principal Investigator: George Capone, M.D.
Application No.: NA_00003324

KENNEDY KRIEGER INSTITUTE
Down Syndrome Clinic
Research Announcement!

WHO: We are recruiting children and adolescents with Down syndrome (ages 10 - 17), in general good health, to participate in a study to examine the effect of an investigational medication (FDA-approved for Alzheimer's Disease). This research study is a double-blind, placebo-controlled study which means that 1/2 those in the study will get the active drug and 1/2 will get placebo. We cannot include individuals with any current psychiatric or neurologic diagnosis other than Down syndrome.

WHY: To determine if this investigational medication helps to improve memory, speech and language function in children and adolescents with Down syndrome.

WHEN: Participation in this study will require at least four 2 to 6 hour visits to the Kennedy Krieger Institute in Baltimore, Maryland, over the course of a 24-week period.

WHAT: Prior to the first visit, caregivers will complete a telephone interview to assess eligibility for the study. Visits will consist of medical and neurologic exams (including a blood draw at the first visit and an EKG at the first and last visit) as well as functional, cognitive and language testing. For females, there will be a blood pregnancy test at the first visit and a urine pregnancy test at the following visits.

Taking the medication as part of this study may cause diarrhea, nausea, vomiting, dizziness, headache, trouble sleeping, decreased appetite, shakiness, weakness and pale coloring. Long-term effects of the medication are not yet known. Participation in this study may provide a personal medical benefit such as improved memory, attention, and/or language function, but there is no guarantee. Each family will receive \$25 for each completed visit to help with the costs of gas and meals.

HOW: If you are interested in participating, please contact us! We look forward to working with you on this study.

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