

An Open-Label Study to Evaluate the Safety of Donepezil Hydrochloride (Aricept®) for up to 1 Year in the Treatment of the Cognitive Dysfunction Exhibited by Children with Down Syndrome - Follow-Up to a 10 Week, Double-Blind, Placebo-Controlled Trial (A2501060)

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Synopsis:

In the light of a variety of evidence and the significant unmet medical need for children with Down Syndrome (DS), it is appropriate to attempt a well-designed study to determine whether donepezil, a cholinesterase inhibitor with the potential to improve central cholinergic function, will benefit these children. If such benefits are proven and donepezil becomes indicated to treat children with DS, use of donepezil in these children would likely become long term. Therefore, data about the safety of long term use of donepezil in this population will be necessary to guide clinical decision-making. This study will collect safety data for 42 weeks for all subjects who complete the study. For approximately half of the subjects, data for an additional 10 weeks of exposure to donepezil in the double blind study will be available, and the final data for these subjects will represent 52 weeks of continuous donepezil exposure for those subjects who complete the study.