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Memory Improvement through Nicotine Dosing (MIND)

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Memory Improvement through Nicotine Dosing (MIND)

This is a Phase II multi-center, placebo-controlled study that will evaluate whether long-term use of transdermal nicotine patches enhances attentional functioning and memory in patients with mild cognitive impairment (MCI). In previous studies, nicotinic stimulation has shown positive cognitive effects in diseases in which attention and/or memory is impaired (e.g., Alzheimer's disease, ADHD, and Tourette's syndrome). A Phase I trial of 67 individuals concluded that the drug was safe and well tolerated. Three hundred participants with MCI (150 in the placebo arm and 150 in the active treatment arm) will be randomly assigned to receive patches with either an active dose of nicotine or placebo for 24 months. Screening will occur over 4 weeks followed by a 24-month treatment period, in addition to a 3-week tapering off period. The study requires a minimum of 2 visits during the screening and baseline period and up to 12 visits during the course of treatment. Participants will be monitored by the study team closely for the duration of the study. Memory, functional, and cognitive measures (Connors Performance Task, Clinical Global Impression of Change, Clinical Dementia Rating, and paragraph recall) also will be evaluated during regular visits to power a subsequent Phase III trial. Enrollment for this trial is open and we continue to screen and enroll additional participants for the MIND trial. Participants do not need to have a diagnosis of MCI in order to be considered eligible for this trial.

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