A combination of galantamine and memantine modifies cognitive function in subjects with amnestic MCI.

Abstract:
Mild cognitive impairment (MCI) is etiologically heterogeneous, and a substantial proportion of MCI subjects will develop different dementia disorders. One subtype of this syndrome, amnestic MCI, occurs preferentially but not exclusively in prodromal AD and is characterized by defined deficits of episodic memory. For a 2-year, double-blinded, placebo-controlled study MCI patients, presenting with an amnestic syndrome but not necessarily based on presumed prodromal AD were randomized. Patients received (a) a combination of 16 mg galantamine plus 20 mg memantine, or (b) 16 mg galantamine alone or (c) placebo. The primary objective was to explore the differential impact of these interventions on the progression to dementia and on cognitive changes as measured by the ADAScog. After recruitment of 232 subjects, the trial was halted before reaching the planned sample size, because safety concerns arose in other studies with galantamine in MCI. This resulted in a variable treatment duration of 2-52 weeks. The statistical analysis plan was amended for studying cognitive effects of discontinuing the study medication, which was done separately for galantamine and memantine, and under double-blind conditions. There was one death, no
unexpected severe adverse events, and no differences of severe adverse events between the
treatment arms. The cognitive changes on the ADAScog were not different among the groups. Only
for the subgroup of amnestic MCI with presumed AD etiology, a significant improvement of ADAScog
score over placebo before the discontinuation of medication was observed, while amnestic MCI
presumably due to other etiologies showed no cognitive changes with broad variation. Cognitive
improvement was numerically larger in the combination treatment group than under galantamine
alone. Patients who received placebo declined as expected. Discontinuation of galantamine, either as
part of the combination regimen or as mono treatment, resulted in a transient decline of the ADAScog
score in amnestic MCI of presumed AD etiology, while discontinuation of Memantine did not change
the cognitive status. In an interrupted trial with amnestic MCI subjects the combination of galantamine
plus memantine were generally well tolerated. In the subgroup of MCI subjects with presumed AD
etiology, a cognitive benefit of a short-term combination treatment of galantamine plus memantine
was observed, and cognitive decline occurred after discontinuation of galantamine.

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