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Cessation versus continuation of galantamine treatment after 12 months of therapy in patients with Alzheimer's disease: a randomized, double blind, placebo controlled withdrawal trial

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Abstract

Galantamine improved symptoms in Alzheimer's disease (AD) patients after 5 to 6 months of treatment. To examine long-term outcomes, this study assessed if continuing of galantamine treatment beyond 12 months delayed further cognitive deterioration. It consisted of two phases: an open label (OL) phase (12 months), followed by a double blind, randomized, placebo controlled withdrawal phase (up to 24 months). Subjects with mild to moderate AD were included in the study and titrated up to 16 mg/day of galantamine. Subjects were eligible to enter the double blind phase if a cognitive decline of <4 points on AD Assessment Scale-cognitive subscale (ADAS-cog)/11 was recorded at the end of the OL phase. The differences between galantamine and placebo in time to dropout were estimated using the Cox proportional hazard model. 47.4% of galantamine and 31.7% of placebo subjects completed the double blind phase. Placebo subjects were more likely to discontinue prematurely than galantamine subjects for any reason (hazard ratio [HR] 1.76, 95% confidence interval [CI] 1.10-2.81, p = 0.02), or lack of efficacy (HR 1.80, 95% CI 1.02-3.18, p = 0.04); no statistically significant difference was seen for a change in ADAS-cog ≥ 4 between treatment groups (HR 1.66, 95% CI 0.78-3.54, p = 0.19). Subjects who responded to 12 months of galantamine treatment benefited from continued drug therapy for up to 36 months. Galantamine was effective in delaying time to cognitive deterioration in subjects with mild to moderate AD. Treatment was generally safe and well tolerated.

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