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Drug for Alzheimer's disease does not appear to slow cognitive decline

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Although there were promising results in a phase 2 trial, patients with mild Alzheimer disease who received the drug tarenflurbil as part of a phase 3 trial did not have better outcomes on measures of cognitive decline or loss of activities of daily living compared to patients who received placebo, according to a study in the December 16 issue of *JAMA*.

A leading theory on the pathophysiology of Alzheimer disease (AD) is the overproduction of amyloid-β (Aβ; a peptide of certain amino acids that appear to be the main constituent of amyloid plaques in the brains of patients with AD), particularly 42 amino acid peptide Aβ42. "Tarenflurbil, a selective Aβ42-lowering agent, demonstrated encouraging results on cognitive and functional outcomes among mildly affected patients in an earlier phase 2 trial," the authors write.

Robert C. Green, M.D., M.P.H., of the Boston University Schools of Medicine and Public Health, and colleagues conducted a large phase 3, randomized trial of tarenflurbil for patients with mild AD to determine its efficacy, safety and tolerability. The study, conducted at 133 trial sites in the United States, included 1,684 participants who were randomized, of whom 1,649 were included in the analysis, and 1,046 completed the 18-month trial. Patients were randomized to tarenflurbil, 800 mg, or placebo, administered twice a day.

The researchers found that tarenflurbil had no beneficial effect on the primary outcomes of cognition and activities of daily living after 18

months. There were also no significant differences on secondary outcomes, which included other AD assessment measures such as quality of life and caregiver burden.

Regarding adverse events, more participants taking tarenflurbil than those taking placebo experienced dizziness, upper respiratory tract infections and anemia.

"Our results are … a reminder that interventions affecting amyloid have not yet been shown to alter the course of AD," the authors conclude.

More information: *JAMA*. 2009;302[23]:2557-2564.

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