

PCSK9 inhibitor evolocumab not associated with decline in memory or cognitive function

19 March 2017

New trial results show that in patients on statin therapy, the addition of evolocumab did not result in a significant change in cognitive function after 19 months of treatment.

A new class of cholesterol lowering drugs, PCSK9 inhibitors, effectively lower LDL cholesterol levels beyond current treatment targets, and new research shows that these lower levels result in a reduction in [adverse cardiovascular events](#), making these drugs attractive treatment options for [patients](#) who do not achieve their target cholesterol level with [statin therapy](#) alone. However, previous research had raised the possibility that a low level of LDL cholesterol and/or use of statins may negatively impact memory and overall cognition. New research led by the TIMI Study Group at Brigham and Women's Hospital in collaboration with Brown University and the University of Geneva reassuringly finds no association between the use of the PCSK9 inhibitor evolocumab and a decline in memory or cognitive function.

The findings were presented at the American College of Cardiology Scientific Sessions on March 18, 2017. Full results of the study are expected to be published in a peer-reviewed journal in the coming months.

"After an average of 19 months of treatment, our data show that changes in memory and cognitive function were very small and similar between patients treated with evolocumab and those treated with placebo," said Robert Giugliano, MD, SM, a senior investigator in the TIMI Study Group and physician in the Cardiovascular Division at BWH. "These data should reassure physicians and patients who may have had questions about the safety of this drug as it pertains to cognitive impairment."

Using a computer tablet-based tool, researchers assessed the executive function, working memory, episodic memory and psychomotor speed of 1,974

patients who were enrolled in EBBINGHAUS, a substudy embedded in the FOURIER trial. FOURIER was designed to evaluate the impact of evolocumab on cardiovascular outcomes in patients on statin therapy, and found that evolocumab significantly reduced cardiovascular events, with a larger effect the longer patients were treated.

For EBBINGHAUS, patients performed baseline cognitive tests at the time of enrollment, and at six, 12 and 24 months. In the primary analysis, researchers compared changes in the baseline measurement in 1,204 patients who had a cognitive assessment on or prior to the first day they received evolocumab or placebo; a secondary analysis compared results in all 1,974 patients, including 770 patients who had baseline testing after the first dose but no later than the week 12 visit.

"We examined tests of potential adverse effects of the treatment on not only memory but also attention and reaction time that are important aspects of cognition that could seriously impact daily functioning," said Brian R. Ott, MD a physician in the Department of Neurology at Rhode Island Hospital and the Alpert Medical School of Brown University, and member of the EBBINGHAUS study steering committee. "We found no significant differences during the course of the study between the active and placebo treatment groups for any of these cognitive domains."

Results of cognitive testing also did not vary by the achieved level of low-density (bad) cholesterol, including the group who were treated with evolocumab and achieved low-density cholesterol below 25 mg/dL, a level that is far below current treatment goals.

In addition to collecting data from the computer tablet-based test, researchers also collected and analyzed information from self-reported patient

assessments of everyday function, and investigator-reported adverse events related to memory and cognition. For both of these measures, there were no significant differences between the [treatment](#) and the placebo groups.

Provided by Brigham and Women's Hospital

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