The use of gantenerumab leads to lower amyloid plaque burden at 116 weeks, but is not associated with slower clinical decline among patients with early Alzheimer disease, according to a study published in the Nov. 16 issue of the *New England Journal of Medicine.*
Randall J. Bateman, M.D., from the Washington University School of Medicine in St. Louis, and colleagues conducted two phase 3 trials involving participants aged 50 to 90 years with mild cognitive impairment or mild dementia due to Alzheimer disease and evidence of amyloid plaques. Overall, 985 and 980 participants in the GRADUATE I and GRADUATE II trials, respectively, were randomly assigned to receive gantenerumab or placebo every two weeks.

The researchers found that the change from baseline in the Clinical Dementia Rating Scale-Sum of Boxes score at week 116 was 3.35 and 3.65 with gantenerumab and placebo, respectively, in the GRADUATE I trial, and 2.82 and 3.01 in the GRADUATE II trial (difference, −0.31 and −0.19, respectively).

The difference in the amyloid level on positron emission tomography (PET) between the gantenerumab group and the placebo group was −66.44 and −56.46 centiloids in the GRADUATE I and II trials, respectively, at week 116; 28.0 and 26.8 percent of the participants receiving gantenerumab in the two trials achieved amyloid-negative status.

Participants receiving gantenerumab across both trials had lower cerebrospinal fluid levels of phosphorylated tau 181 and higher levels of amyloidβ42 than those receiving placebo; the two groups had similar accumulation of aggregated tau on PET.

"The use of the antiamyloid antibody gantenerumab did not lead to a slower decline in cognitive function than placebo," the authors write.


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