

Preliminary study: Drug may be safe in those with mild cognitive impairment, mild dementia

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A small, preliminary study of an investigational new drug being studied for mild cognitive impairment and mild dementia associated with

Alzheimer's disease suggests it is safe and may be associated with improvements in executive function, thinking and memory skills. The study is released today, March 31, 2022, and will be presented at the American Academy of Neurology's 74th Annual Meeting being held in person in Seattle, April 2 to 7, 2022 and virtually, April 24 to 26, 2022. The drug, called SAGE-718, is also in clinical trials for the treatment of cognitive impairment associated with Parkinson's disease and Huntington's disease.

"Cognitive impairment is often one of the earliest signs of Alzheimer's disease, can be very difficult for patients and their families, and represents an area of great unmet medical need," said study author Aaron Koenig, MD, of Sage Therapeutics in Cambridge, Mass., the maker of the investigational drug. "These results support further research with larger numbers of people to determine whether this therapy is safe and effective in treating [cognitive impairment](#) in Alzheimer's disease and related disorders and in improving how well people can function independently in their [everyday lives](#)."

The study involved 26 people with an average age of 67. They had an average score of 20.7 points on a common cognitive test, indicating cognitive performance consistent with [mild cognitive impairment](#) or mild dementia. The participants took SAGE-718 daily for two weeks and were then followed for another two weeks. They completed tests of thinking and memory at the beginning of the study, at the end of treatment, and after one month. Both the participants and researchers knew that SAGE-718 was being administered.

The study was designed mainly to gather data on the drug's safety. There were no serious side effects of the drug. Five people had mild or moderate side effects believed to be related to the drug, such as headache or constipation.

After one month, the participants' scores on the cognitive test had improved by an average of 2.3 points, to 22.8 points.

Koenig said some participants also had improvement in assessments of how well they were able to complete their [daily activities](#), especially in complex activities such as using a computer, carrying out household chores, and managing their medications. This coincided with consistent improvement on multiple tests of executive functioning that were administered during the trial.

Koenig said, "If replicated in future studies, such improvements suggest that this drug may eventually provide meaningful benefits to people in their everyday lives."

SAGE-718 is a type of drug called a positive allosteric modulator of N-methyl-D-aspartate (NMDA) receptors.

The study's limitations include its [small size](#) and that participants and researchers knew that the drug was being administered, which could lead to bias.

More information: www.aan.com/events/annual-meeting

Provided by American Academy of Neurology

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