

Ginkgo proves ineffective in preventing dementia, Alzheimer's disease

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One of the most widely used herbal supplements for improving memory and cognition has no impact on the development of dementia or Alzheimer's disease, according to new results from a \$30 million, multi-center study.

The Ginkgo biloba for the Evaluation of Memory (GEM) Study was the largest clinical trial ever to evaluate the effects of the dietary supplement ginkgo biloba (ginkgo) on the occurrence of dementia. The study tested the effectiveness of 120 milligrams (mg) of ginkgo twice daily versus placebo in lowering the incidence of dementia and Alzheimer's in normal, elderly people and those with mild cognitive impairment.

Results from the study show that 240 mg of ginkgo daily has no effect on the onset of dementia or development of Alzheimer's. The study appears in this week's issue of the *Journal of the American Medical Association*.

Many people today use ginkgo leaf extracts hoping to improve memory, to treat or help prevent Alzheimer's and other types of dementia, to decrease intermittent claudication (leg pain caused by narrowing arteries) and to treat sexual dysfunction, multiple sclerosis, tinnitus, and other health conditions. In Europe and the United States, ginkgo supplements are among the best-selling herbal medications and it consistently ranks as a top medicine prescribed in France and Germany.

"Alzheimer's disease is a devastating disease affecting large numbers of

older adults," said Gregory Burke, M.D., M.Sc., the lead investigator for the Wake Forest University Baptist Medical Center clinical site. "Our best strategy is to prevent dementia before it begins."

The study was conducted primarily to determine if ginkgo would decrease the incidence of all types of dementia and, more specifically, reduce the incidence of Alzheimer's. The study also aimed to evaluate ginkgo for its effects on overall cognitive decline, functional disability, incidence of cardiovascular disease and stroke, and total mortality.

The results were disappointing and surprising, said Burke and Jeff Williamson, M.D., M.H.S., principal investigator for the GEM Study Clinical Coordinating Center at Wake Forest Baptist.

"In addition to its widespread use based on the belief that it helps memory function," Williamson said, "Ginkgo biloba had enough promising circumstantial evidence from laboratory and animal studies and enough safety information to warrant a full-scale test in humans."

Dementia is a form of brain disease that can seriously affect a person's ability to carry out daily activities. It is caused by many conditions, some of which are reversible. Alzheimer's is one of the most common forms of dementia in older people, affecting nearly 4.5 million Americans, according to the National Institute on Aging. It is an incurable disease with a slow progression beginning with mild memory loss and ending with severe brain damage and death.

The GEM Study was conducted at four clinical sites: Wake Forest Baptist, the University of Pittsburgh, Johns Hopkins University, and the University of California-Davis.

Investigators followed a total of 3,069 participants age 75 or older, who had either normal cognition or mild cognitive impairment. Participants

were randomized to receive twice-daily doses of either 120 mg of ginkgo extract or placebo. The dose of ginkgo was selected based on prior clinical study results that found 120 mg twice daily to be the most effective dose. The ginkgo product used in the study was supplied by Schwabe Pharmaceuticals and is sold in the United States as Ginkgold Max™, under the Nature's Way label.

Patients were followed for an average of about six years, with a maximum of just over seven years. During the study, 523 participants were diagnosed with dementia, 246 in the placebo group and 277 in the ginkgo group, leading researchers to declare that ginkgo showed no overall effect for reducing all types of dementia or Alzheimer's.

"It is very unlikely that ginkgo biloba is effective at any dose over a five-year period and in anyone over 75 years old," Williamson said. "It is also ineffective in people with signs of early memory loss. What is not known yet is whether the effect of ginkgo biloba might require taking the drug for many, many years, say 15 years, before there is even a sign of memory loss."

For the millions of people spending their money on over-the-counter ginkgo for the perceived promise of protection from dementia and Alzheimer's, Williamson suggests they spend their money elsewhere, while remaining mentally and physically active.

And though ginkgo failed to perform as hoped, Williamson explained that the trial was valuable in many ways to the scientific community. The study experience itself demonstrates the feasibility of conducting large dementia prevention trials in older adults, the researchers said.

"One of the most important findings from this study is that we can recruit and follow adequate numbers of volunteers for this purpose, even in the rapidly growing population of people over age 75," he said. "This

will be critical for the most cost-effective use of scarce Medicare dollars in the future.

"Secondly, we are already learning a lot of new information from the GEMS volunteers about how dementia develops and how not all memory change is a sign of impending dementia," Williamson added.

Source: Wake Forest University Baptist Medical Center

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