



Long-term use of standardised ginkgo biloba extract for the prevention of Alzheimer's disease (GuidAge): a randomised placebo-controlled trial

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Résumé en anglais

Background Prevention strategies are urgently needed to tackle the growing burden of Alzheimer's disease. We aimed to assess efficacy of long-term use of standardised ginkgo biloba extract for the reduction of incidence of Alzheimer's disease in elderly adults with memory complaints.

Methods In the randomised, parallel-group, double-blind, placebo-controlled GuidAge clinical trial, we enrolled adults aged 70 years or older who spontaneously reported memory complaints to their primary-care physician in France. We randomly allocated participants in a 1:1 ratio according to a computer-generated sequence to a twice per day dose of 120 mg standardised ginkgo biloba extract (EGb761) or matched placebo. Participants and study investigators and personnel were masked to study group assignment. Participants were followed-up for 5 years by primary-care physicians and in expert memory centres. The primary outcome was conversion to probable Alzheimer's disease in participants who received at least one dose of study drug or placebo, compared by use of the log-rank test. This study is registered with ClinicalTrials.gov, number NCT00276510.

Findings Between March, 2002, and November, 2004, we enrolled and randomly allocated 2854 participants, of whom 1406 received at least one dose of ginkgo biloba extract and 1414 received at least one dose of placebo. By 5 years, 61 participants in the ginkgo group had been diagnosed with probable Alzheimer's disease (1.2 cases per 100 person-years) compared with 73 participants in the placebo group (1.4 cases per 100 person-years; hazard ratio [FIR] 0.84, 95% CI 0.60-1.18; $p=0.306$), but the risk was not proportional over time. Incidence of adverse events was much the same between groups. 76 participants in the ginkgo group died compared with 82 participants in the placebo group (0.94, 0.69-1.28; $p=0.68$). 65 participants in the ginkgo group had a stroke compared with 60 participants in the placebo group (risk ratio 1.12, 95% CI 0.77-1.63; $p=0.57$). Incidence of other haemorrhagic or cardiovascular events also did not differ between groups. Interpretation Long-term use of standardised ginkgo biloba extract in this trial did not reduce the risk of progression to Alzheimer's disease compared with placebo.

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