A 24-month, double-blind, placebo-controlled multicentre pilot study of the efficacy and safety of nicergoline 60 mg per day in elderly hypertensive patients with leukoaraiosis.


Department of Neurology at the Centres Hospitaliers Universitaires de Toulouse, France. The French Study Group of Leukoaraiosis.

In this pilot study, 72 non-demented and non-depressive elderly hypertensive patients with evidence of leukoaraiosis on cerebral computed tomography scan (Rezek score: > 16) were randomly assigned to receive either nicergoline 30 mg b.i.d. (n = 36) or a placebo (n = 36) for 24 months. All patients received antihypertensives and their hypertension was controlled under treatment. They were evaluated by nine neuropsychological tests exploring memory, concentration, verbal and motor performances, administered at baseline and at every six-month interval during the study period. At baseline, the two groups were comparable for all demographic and clinical characteristics, including cognitive functions, except for the delayed recall of the Auditory Verbal Learning Test (AVLT), which was better in the placebo group (P = 0.04). Changes in scores over time were compared between the two groups. At the last visit, patients on nicergoline (n = 31) were found to have deteriorated less or to have improved more on test scores than the patients on placebo (n = 30). Significant differences were observed for memory function (AVLT short term recall, P = 0.026; AVLT delayed recall, P = 0.013; and, Benton Visual Retention Test, P = 0.002) and attention and concentration (Letter Cancellation Test, P = 0.043; and, WAIS-R Digit Symbol subtest, P = 0.006). The Rezek score remained unchanged in the two groups. Tolerance of nicergoline was similar to that of placebo. In conclusion, this study shows that nicergoline 30 mg b.i.d. administered over a 24-month period attenuates the deterioration in cognitive functions in elderly hypertensive patients with leukoaraiosis. Whether these effects were specific for this type of white matter changes could not be determined in the context of this pilot study. Copyright 1999
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