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ML601 in minimal cognitive impairment

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Background & Aim: Minimal cognition impairment (MCI) is characterized by declined cognitive function greater than that of expected for person's life. The clinical significance of this condition is its possible progression to dementia. Currently there is no approved therapy for MCI. ML601 (NeuroAid) is natural neuroprotective medication that has shown promising effects in different diseases including Alzheimer's disease. Accordingly, we conducted this randomized, double-blind, and placebo controlled study to evaluate the efficacy and safety of ML601 (NeuroAid) in patients with MCI.

Methods: Seventy-two (72) patients with MCI diagnosis according to Peterson et al. were recruited. Eligible participants were randomly assigned to each group to receive MLC601 capsule or placebo three times daily and they were prospectively followed for 6 months. Global cognitive function evaluation was performed at baseline, 3-month and 6-month follow-up visits. Global cognitive function was assessed with MMSE and ADAS-cog score.

Results: Seventy (70) patients completed the study. There were finally 34 patients in MLC601 group and 36 patients in placebo group. The mean (SD) age of MLC601 group and placebo group were 70.8 (± 3.69) and 70.2 (± 3.3), respectively. The mean changes (\pm SD) in cognition scores over 6 months in the MLC601 group were -2.26 (± 3.42) for MMSE and 3.82 (± 6.16) for ADAS-cog score and in placebo group were -2.66 (± 3.43) for MMSE and 4.41 (± 6.66) for ADAS-cog score. The cognition changes based on both MMSE and ADAS-cog score were statistically significant between placebo and ML601 groups (p value < 0.001). Only 5 (14.7%) patients reported side effects and the most commonly reported side effects were gastrointestinal.

Conclusion: In our study, ML601 has shown promising efficacy and acceptable side effects for MCI patients but the result of this study needs to be replicated in other studies.

Biography

Hossein Pakdaman graduated in Neurology from the Pennsylvania and Henry Ford University in 1976. He is Professor of Neurology affiliated to Shahid Beheshti University School of Medicine, since 1990, President of Iranian Neurological Association, since 1991, and Director of Iranian Neurological Board Examination, since 1978. Also, he has published more than 40 papers in international journals and is Chairman of Iranian Journal of Neurology, since 1998.

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