

Comparing the efficacy and safety of *Crocus sativus* L. with memantine in patients with moderate to severe Alzheimer's disease: a double-blind randomized clinical trial.

OBJECTIVES:

Limited pharmacological options are available for the management of Alzheimer's disease (AD) in severe stages. Cognitive-enhancing properties of saffron, the dried stigma of *Crocus sativus* L., have been evidenced in different studies. We aimed to compare the efficacy and safety of saffron extract versus memantine in reducing cognitive deterioration of patients with moderate to severe AD.

METHODS:

In this randomized double-blind parallel-group study, 68 patients with moderate to severe AD (Mini-Mental State Examination score of 8-14) received memantine (20 mg/day) or saffron extract (30 mg/day) capsules for 12 months. Participants were evaluated every month by Severe Cognitive Impairment Rating Scale (SCIRS) and Functional Assessment Staging (FAST) in addition to recording the probable adverse events.

RESULTS:

Both treatment groups showed similar outcomes as demonstrated by insignificant effect for time \times treatment interaction on SCIRS scores [$F(2.95, 194.78) = 2.25, p = 0.08$]. There was no significant difference between the two groups in the scores changes from baseline to the endpoint on SCIRS ($p = 0.38$) and FAST ($p = 0.87$). The frequency of adverse events was not significantly different between the two groups as well.

CONCLUSIONS:

In addition to its favorable safety profile, 1-year administration of saffron extract capsules showed to be comparable with memantine in reducing cognitive decline in patients with moderate to severe AD. Confirmatory studies with larger sample sizes and longer follow-up periods are warranted.