Green plants of Life

Giyahan Sabz Zendegi

گیاهان سبز زندگی

# Clinical Trials and Research of Saffron Extract

## Effects of Saffron Extract and its Constituents on Alzheimer

| Alzheimer's Clinical Trials | | | | | |
|---|---|---|---|---|---|
| **No** | **Date** | **Saffron Compared with** | **Duration** | **Selected** | **Tested** |
| **1** | 2010 | Placebo | 16 Week | 82 | 46 |
| **2** | 2009 | Donepezil | 22 Week | 91 | 54 |
| **3** | 2014 | Memantine | 12 Month | 114 | 68 |

# Contents



## 1. Saffron in Phytotherapy: Pharmacology and clinical uses

Wiener Medizinische Wochenschrift (WMW) 2007; 157: 315-319

*Mathias Schmidt, Georges Betti & Andreas Hensel*

***Themenschwerpunkt***
***Published: July 2007***
*Wien Med Wochenschr* **157,** 315 (2007). https://doi.org/10.1007/s10354-007-0428-4

## Summary:

Saffron (stigmates of Crocus sativus L.) has been used for medicinal purposes for millenaries. Throughout history, uses against cancer and depressive mood can regularly be identified. These applications have also been in the focus of modern research. Promising and selective anti-cancer effects have been observed in vitro and in vivo, but not yet in clinical trials. Antidepressant effects were found in vivo and in clinical pilot studies. Saffron extracts thus have the potential to make a major contribution to rational phytotherapy.

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# 2. Saffron in the treatment of patients with mild to moderate Alzheimer's disease:

a 16 - week, randomized and placebo- controlled trial

Journal of Clinical Pharmacy and Therapeutics (2010) doi: 10.1111/j. 1365- 2710.2009.01133.x

**S. Akhondzadeh PhD, M. Shafiee-Sabet MD, M. H. Harirchian——————————— MD, M. Togha——————————— MD, H. Cheraghmakani——————————— MD, S. Razeghi MSc, S. Sh. Hejazi§ MD, M. H. Yousefi§ MD, R. AlimardaniMD, A. Jamshidi– PhD, F. Zare* MD and A. Moradi* MD**

*Psychiatric Research Center, Roozbeh Hospital, Tehran University of Medical Sciences, Tehran, Institute of Medicinal Plants (ACECR), Tehran, Department of Neurology, Tehran University of Medical Sciences, Tehran, §Department of Neurology, Qom University of Medical Sciences, Qom and –Office for Herbal Drugs, Ministry of Health and Medical Education, Tehran, Iran*

**ABSTRACT:**

What is known: Herbal medicines have been used in the treatment of behavioural and psychological symptoms of dementia but with variable response. Crocus sativus (saffron) may inhibit the aggregation and deposition of amyloid b in the human brain and may therefore be useful in Alzheimer's disease (AD). Objective: The goal of this study was to assess the efficacy of saffron in the treatment of mild to moderate AD. Methods: Forty-six patients with probable AD were screened for a 16-week, double-blind study of parallel groups of patients with mild to moderate AD. The psychometric measures, which included AD assessment scale-cognitive subscale (ADAS-cog), and clinical dementia rating scale-sums of boxes, were performed to monitor the global cognitive and clinical profiles of the patients. Patients were randomly assigned to receive capsule saffron 30 mg ⁄ day (15 mg twice per day) (Group A) or capsule placebo (two capsules per day) for a 16-week study.

## Results:

After 16 weeks, saffron produced a significantly better outcome on cognitive function than placebo (ADAS-cog: F = 4Æ12, d.f. = 1, P = 0Æ04; CDR: F = 4Æ12, d.f. = 1, P = 0Æ04). There were no significant differences in the two groups in terms of observed adverse events. What is new and conclusion: This double-blind, placebo-controlled study suggests that at least in the short-term, saffron is both safe and effective in mild to moderate AD. Larger confirmatory randomized controlled trials are called for.

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## 3. A 22 week, multicenter, randomized, double-blind controlled trial of Crocus sativus in the treatment of mild-to-moderate Alzheimer's disease.

a. Original Investigation, Psychopharmacology 2010: 207: 637-643

**Shahin Akhondzadeh & Mehdi Shafiee Sabet & Mohammad Hossein Harirchian & Mansoreh Togha & Hamed Cheraghmakani & Soodeh Razeghi & Seyyed Shamssedin Hejazi & Mohammad Hossein Yousefi & Roozbeh Alimardani & Amirhossein Jamshidi & Shams-Ali Rezazadeh & Aboulghasem Yousefi & Farhad Zare & Atbin Moradi & Ardalan Vossoughi**


- **Received: 29 June 2009**
- **Accepted: 30 September 2009**
- **Published online: 20 October 2009**


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### Abstract:

Rationale There is increasing evidence to suggest the possible efficacy of Crocus sativus (saffron) in the management of Alzheimer's disease (AD). Objective The purpose of the present investigation was to assess the efficacy of C. sativus in the treatment of patients with mild-to-moderate AD. Methods Fifty-four Persian-speaking adults 55 years of age or older who were living in the community were eligible to participate in a 22-week, double-blind study of parallel.


## 4. 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 wiley online Library Human Psychopharmacology 2014: 29: 351-359.

**Mehdi Farokhnia , Mehdi Shafiee Sabet , Negar Iranpour, Amirhossein Gougol, Habibeh Yekehtaz, Roozbeh Alimardani, Farzaneh Farsad, Maryam Kamalipour and Shahin Akhondzadeh**

*Psychiatric Research Center, Roozbeh Hospital, Tehran University of Medical Sciences, Tehran, Iran*

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### Abstract:

**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 × 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. 

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