

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effect of Saffron Versus Memantine in patients with severe Alzheimer's disease: randomized double-blind placebo-controlled study

Protocol summary

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Summary

The objective of this study was to compare the efficacy and safety of Capsule of Crocus sativus to memantine, in patients with severe Alzheimer's disease, over 52 weeks. Patients with severe Alzheimer's disease aged between 60-95 years will be randomized to Capsule memantine (10 mg twice per day) or Capsule of Crocus Sativus (15 mg twice per day) for 1 year. The main efficacy measures will be the change in the Scirs and FAST scores compared to baseline at week 52. Secondary outcomes will be change in scores at Scirs and FAST every 4 weeks. In addition, side effects will be systematically recorded

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203051556N39**

Registration date: **2012-03-11, 1390/12/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-11, 1390/12/21

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

Scientific title

Effect of Saffron Versus Memantine in patients with severe Alzheimer's disease: randomized double-blind placebo-controlled study

Public title

Comparison of effect of Saffron versus memantine in patients with severe Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: A diagnosis of Alzheimer's disease according to the criteria of National Institute of Neurological and Communicative Disorders and Stroke and Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA); Presence of severe dementia: MMSE8-14]. Exclusion Criteria: Concomitant diseases such as hypertension, congestive heart failure, non-insulin dependent diabetes mellitus and hypothyroidism; Patients with evidence of other neurodegenerative disorders; Any cardiovascular disease likely to prevent completion of the study; Clinically significant psychiatric diseases; Urinary outflow obstruction; Active peptic ulcer; Any history of epilepsy;

Significant drug or alcohol misuse; Drugs with anticholinergic effects or cholinomimetic effects

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2012-02-20, 1390/12/01

Ethics committee reference number

16507

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Alzheimer's severity

Timepoint

Every month

Method of measurement

SCIRS

Secondary outcomes

1

Description

Severity of Alzheimer

Timepoint

Every Month

Method of measurement

FAST

Intervention groups

1

Description

capsule Saffron 15 mg twice per day for one year

Category

Treatment - Drugs

2

Description

capsule memantine 10 mg twice per day for one year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Research Center, Roozbeh Hospital

Full name of responsible person

Shahin Akhondzadeh

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Keshavarz Boulevard

City

Tehran

Grant name

Grant code / Reference number

16507

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Professor of clinical neuropsychopharmacology

Other areas of specialty/work**Street address**

Roazbeh hospital

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty