

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of saffron (*Crocus sativus*) capsules for patients with mild cognitive impairment: a double-blind, placebo-controlled study

Protocol summary

Study aim

Investigating the effect of saffron (*Crocus sativus*) capsules in patients with mild cognitive impairment

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Rey-AVLT \leq 8 - Radiological Criteria: Bilateral Hippocampal volume \leq ۳.۶۳cc - Radiological Criteria: Entorhinal cortex thickness \leq ۳.۲۵ m. Exclusion criteria: The presence of an uncontrolled acute or chronic physical illness or a marked disturbance in the patient's tests - The presence of any neurological disease that leads to cognitive disorders, such as epilepsy or developmental and neurometabolic disorders and brain system inflammations - History of moderate and severe head trauma - Uncontrolled acute or chronic psychiatric illness including psychosis or mood disorder and severe depression - Any history of drug or alcohol abuse - Severe visual or motor impairment that prevents the implementation of the virtual reality navigation test - The presence of any contraindications to MRI during the study.

Intervention groups

Control group: patients take placebo capsules twice a day - Intervention group: patients take saffron capsules with a dose of 15 mg twice a day.

Main outcome variables

Severity of mild cognitive impairment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N148**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

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

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of saffron (*Crocus sativus*) capsules for patients with mild cognitive impairment: a double-blind, placebo-controlled study

Public title

The effect of saffron in patients with mild cognitive impairment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Rey-AVLT<=8 Radiological Criteria: Bilateral Hippocampal volume <= ۳.۶۳cc Radiological Criteria: Entorhinal cortex thickness <=۳.۲۵ m

Exclusion criteria:

The presence of an uncontrolled acute or chronic physical illness or a marked disturbance in the patient's tests The presence of any neurological disease that leads to cognitive disorders, such as epilepsy or developmental and neurometabolic disorders and brain system inflammations History of moderate and severe head trauma Uncontrolled acute or chronic psychiatric illness including psychosis or mood disorder and severe depression Any history of drug or alcohol abuse Severe visual or motor impairment that prevents the implementation of the virtual reality navigation test The presence of any contraindications to MRI during the study

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-12-18, 1401/09/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.828

Health conditions studied

1

Description of health condition studied

Mild cognitive impairment

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Severity of mild cognitive impairment

Timepoint

Weeks 0, 6, 12

Method of measurement

By Rey AVLT , (MoCA (Montreal Cognitive Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Control group: patients take placebo capsules twice a day

Category

Placebo

2

Description

Intervention group: patients take saffron capsules with a dose of 15 mg twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

City

Tehran

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1333715914

Phone

+98 21 5541 2222

Email

mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

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afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2023 to 2028

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource of data

From where data/document is obtainable

Prof. Shahin Akhondzadeh

What processes are involved for a request to access data/document

By E-mail

Comments