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<=8 - Radiological Criteria: Bilateral Hippocampal volume <= ۴.۶۳cc - Radiological Criteria: Entorhinal cortex thinking <=۴.۲۵ 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 thinking <=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
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Tehran
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1333715914
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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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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
Street address
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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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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