

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluating the efficacy and safety of Saffron add-on treatment in the improvement of motor and depressive symptoms in patients with Parkinson's disease: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

The effect of Saffron on motor and depressive symptoms in patients with Parkinson's disease

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: Age 30-75 - Known case for Parkinson's disease- Diagnosis of depression, mild to moderate according to HAM-D. Exclusion criteria: Diagnosis or history of other neurological diseases such as epilepsy and Alzheimer's disease - Diagnosis or history of vascular disorders, dementia and stroke - Diagnosis or history of other psychiatric disorders such as bipolar disorder - Addiction - Antipsychotic use in the past year - Diagnosis of central nervous system infections such as meningitis during the study - Use of Linezolid at the beginning of the study, or during the study

Intervention groups

Control group: routine Parkinson's disease drug with the dose specified by the doctor + placebo capsule twice a day - Intervention group: routine Parkinson's disease drug with the dose specified by the doctor + Saffron capsule (15 mg) twice a day. The routine drug used does not change, because these drugs are effective on dopamine and the change in the dose of these drugs can affect the mood of the patients and as a result, the main effect of saffron cannot be determined.

Main outcome variables

Severity of depression and motor symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N145**

Registration date: **2022-08-15, 1401/05/24**

Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**

Update count: **0**

Registration date

2022-08-15, 1401/05/24

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

2022-10-23, 1401/08/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the efficacy and safety of Saffron add-on treatment in the improvement of motor and depressive symptoms in patients with Parkinson's disease: A randomized, double-blind, placebo-controlled clinical trial

Public title
The effect of Saffron on motor and depressive symptoms in patients with Parkinson's disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 30-75 Diagnosis for Parkinson's disease by Neurologist Diagnosis of depression, mild to moderate according to HAM-D
Exclusion criteria:
 Age outside the range of 30-75 years Diagnosis or history of other neurological diseases such as epilepsy and Alzheimer's disease Diagnosis or history of vascular disorders, dementia and stroke Diagnosis or history of other psychiatric disorders such as bipolar disorder Addiction Antipsychotic use in the past year Diagnosis of central nervous system infections such as meningitis during the study Use of Linezolid at the beginning of the study, or during the study

Age
From **30 years** old to **75 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 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
 2022-03-19, 1400/12/28
Ethics committee reference number
 IR.TUMS.MEDICINE.REC.1401.319

Health conditions studied

1

Description of health condition studied
Severity of depressive and motor symptoms

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Severity of depressive and motor symptoms

Timepoint
Weeks 0 - 4 - 8

Method of measurement
By Hamilton Depression Rating Scale & MDS-UPDRS III

Secondary outcomes
empty

Intervention groups

1

Description

Control group: routine Parkinson's disease drug with the dose specified by the doctor + placebo capsule twice a day

Category

Placebo

2

Description

Intervention group: routine Parkinson's disease drug with the dose specified by the doctor + Saffron capsule (15 mg) twice a day. The routine drug used does not change, because these drugs are effective on dopamine and the change in the dose of these drugs can affect the mood of the patients and as a result, the main effect of saffron cannot be determined.

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

Province

Tehran

Postal code

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, Qhods St.,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Position
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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