# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 Hamiltion 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

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**Postal code**

1333715914

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+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., 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?**

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

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

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## Person responsible for updating data

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**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Shahin Akhondzadeh
**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**