

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### **Evaluation the effect of saffron supplementation on some indices of inflammation and oxidative stress, stage of disease, motor and non-motor symptoms, mental health, cognitive impairment, intestinal permeability, gastrointestinal symptoms, appetite, fatigue, quality of life, and sleep quality in patients with Parkinson's disease: A triple blind randomized controlled clinical trial**

#### **Protocol summary**

##### **Study aim**

Evaluation the effect of saffron supplementation on some indices of inflammation and oxidative stress, stage of disease, motor and non-motor symptoms, mental health, cognitive impairment, intestinal permeability, gastrointestinal symptoms, appetite, fatigue, quality of life, and sleep quality in patients with Parkinson's disease

##### **Design**

A controlled, randomized, triple-blind clinical trial with parallel groups, phase 3 on 92 patients with Parkinson's disease. Randomization based on the permuted blocks randomization according to sex and stage of disease

##### **Settings and conduct**

The participants will be selected from patients with Parkinson's disease who refer to the neurologist's clinic in Isfahan city. All patients will be asked to return any unused tablets at each visit. At the beginning and end of the study, all outcomes will be measured and recorded.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age of 45 years old or more; Diagnosis of Parkinson's disease based on United Kingdom PD Society Brain Bank (UKPDSBB) criteria; Having the Hoehn and Yahr score less than 5; BMI equal or less than 40; Non-inclusion criteria: Adherence to a specific diet or consumption of saffron supplement in the last 3 months; Patients with other neurodegenerative diseases such as Huntington's disease, Wilson's disease; Central nervous system infections such as meningitis; having a Hoehn and Yahr score of 5 out of 5; Patients with a history of saffron allergy;

##### **Intervention groups**

Intervention: 100 mg/day Saffron supplementation for 12 weeks; Control: 100 mg/day lactose powder

supplementation for 12 weeks.

##### **Main outcome variables**

indices of inflammation and oxidative stress, stage of disease, motor and non-motor symptoms, mental health, cognitive impairment, intestinal permeability, gastrointestinal symptoms, appetite, fatigue, quality of life, and sleep quality

#### **General information**

##### **Reason for update**

increasing the sample size due to possible dropout and correction of omitted items

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20121216011763N61**

Registration date: **2024-03-05, 1402/12/15**

Registration timing: **prospective**

Last update: **2025-09-07, 1404/06/16**

Update count: **2**

##### **Registration date**

2024-03-05, 1402/12/15

##### **Registrant information**

##### **Name**

Gholamreza Askari

##### **Name of organization / entity**

Isfahan University of Medical Sciences

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 31 1792 2110

##### **Email address**

askari@mui.ac.ir

**Recruitment status**  
**Recruitment complete**  
**Funding source**

**Expected recruitment start date**  
2024-06-21, 1403/04/01

**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**  
Evaluation the effect of saffron supplementation on some indices of inflammation and oxidative stress, stage of disease, motor and non-motor symptoms, mental health, cognitive impairment, intestinal permeability, gastrointestinal symptoms, appetite, fatigue, quality of life, and sleep quality in patients with Parkinson's disease: A triple blind randomized controlled clinical trial

**Public title**  
The effect of saffron supplementation on Parkinson's disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Agreement for participation in the study Age of 45 years old or more Diagnosis of Parkinson's disease based on United Kingdom PD Society Brain Bank (UKPDSBB) criteria Having the Hoehn and Yahr score less than 5 BMI equal or less than 40

**Exclusion criteria:**  
Adherence to a specific diet or consumption of saffron supplement in the last 3 months Patients with other neurodegenerative diseases such as Huntington's disease, Wilson's disease Central nervous system infections such as meningitis Having a Hoehn and Yahr score of 5 out of 5 Patients with a history of saffron allergy

**Age**  
From **45 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **92**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization of patients will be done using a four-block randomization method. For this purpose, people will be classified into 4 states based on the variables of gender and stage of the disease and people with the same states will be randomly assigned to intervention and placebo groups in a 1:1 ratio. Block randomization will be done using a list of random numbers generated by the website <https://www.sealedenvelope.com/simple> and by an independent researcher.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
This study is a triple blind clinical trial. The saffron supplement and its placebo will be packed identically in terms of (color, shape and smell) in similar boxes. In order to carry out this research in a triple blind manner, patients, researchers who are responsible for interview, sampling and evaluating tests and statistical analyzes will be blinded.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Sciences

**Street address**  
Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

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**Province**  
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**Postal code**  
8174673461

**Approval date**  
2024-01-20, 1402/10/30

**Ethics committee reference number**  
IR.MUI.PHANUT.REC.1402.072

**Health conditions studied**

**1**

**Description of health condition studied**  
Parkinson's disease

**ICD-10 code**  
G20

**ICD-10 code description**

Parkinson's disease

**Primary outcomes****1****Description**

Stage of disease

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Hoehn and Yahr scale

**2****Description**

serum level of C-reactive protein (CRP)

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Biorex Fars kit

**3****Description**

Symptoms of Parkinson's disease (motor and non-motor)

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Using the MDS-UPDRS questionnaire

**4****Description**

Total antioxidant capacity

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Kiazist biochemical kit

**5****Description**

Activity of Catalase enzyme

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Kiazist biochemical kit

**6****Description**

Malondialdehyde (MDA) serum level

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Kiazist biochemical kit

**7****Description**

Glutathione serum level

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Kiazist biochemical kit

**8****Description**

Zonulin serum level

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Enzyme-linked immunosorbent assay (ELISA) kit

**Secondary outcomes****1****Description**

Quality of Life

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Parkinson's Disease Questionnaire - 39

**2****Description**

Mental health (Depression, stress, anxiety)

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

DASS-21questionnaire

**3****Description**

sleep quality

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

PDSS questionnaire

**4****Description**

Cognitive status

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

AMT questionnaire

**5****Description**

Anthropometric indices

**Timepoint**

At baseline and after 12 weeks

**Method of measurement**

Seca scale and portable stadiometer

## 6

### **Description**

Gastrointestinal symptoms

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Visual Analogue Scale

## 7

### **Description**

Appetite

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

SNAQ Questionnaire

## 8

### **Description**

Fatigue

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

PFS-16 Questionnaire

## 9

### **Description**

Blood pressure

### **Timepoint**

At baseline and after 12 weeks

### **Method of measurement**

Digital sphygmomanometer

## **Intervention groups**

### 1

#### **Description**

Intervention group: For 12 weeks, daily intake of one tablet containing 100 mg of first-class Sargol saffron prepared by Mojtahedi Company (preparation of tablets will be done at the Faculty of Pharmacy)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: For 12 weeks, daily intake of one tablet containing 100 mg of lactose powder prepared by Pak Azma Company (preparation of the tablets will be done at the Faculty of Pharmacy)

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

#### **Name of recruitment center**

Neurology clinic of Al-Zahra Hospital

#### **Full name of responsible person**

Dr. Gholamreza Askari

#### **Street address**

Soffeh Blvd

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#### **Postal code**

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### 2

#### **Recruitment center**

##### **Name of recruitment center**

Neurology clinic of Khorshid Hospital

##### **Full name of responsible person**

Dr. Gholamreza Askari

##### **Street address**

khorshid medical educational research complex,  
Ostandari Street, Isfahan

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr. Gholamreza Askari

##### **Street address**

Deputy of Research & Technology of Isfahan  
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#### **Grant name**

Deputy of Research & Technology of Isfahan University  
of Medical Sciences

**Grant code / Reference number**

IR.MUI.PHANUT.REC.1402.072

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Esfahan University of Medical Sciences

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**Position**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to  
make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to  
make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to  
make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available  
**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available