Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Scien
Street address
Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran
City
Isfahan
Province
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
81746 75731
Phone
+98 31 3222 2127
Email
askari@mui.ac.ir

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
City
Isfahan
Province
Isfehan
Postal code
8145833117
Phone
+98 31 3222 2127
Email
Askari@mui.ac.ir

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 University of Medical Sciences, Hezar Jarib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3060
Email
askari@mui.ac.ir
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

Street address
Deputy of Research & Technology of Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3060

Email
askari@mui.ac.ir

Person responsible for scientific 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

Street address
Deputy of Research & Technology of Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City
اصفهان

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3060

Email
askari@mui.ac.ir

Person responsible for updating data

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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Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3060

Email
askari@mui.ac.ir

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