Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the Efficacy of Crocin on Movement Disorders and Neuronal Oxidative Stress of Parkinson's Disease; A Double-blind, Randomized, Placebo-controlled Clinical Trial

Protocol summary

Study aim
Investigating the effect of crocin on Parkinson's disease and its clinical symptoms

Design
A clinical trial with the control group, with parallel groups, blinded, randomized, on 54 patients.

Settings and conduct
The patient admission process begins at the Neurology Clinic of Imam Hossein (AS) Hospital and Shahada Tajrish Hospital by examining the level of bradykinesia, cognitive disorders, tremors, and muscle stiffness (Rigidity) of the patients. The patients included in the study are fully aware of the conditions of the trial and their written consent is required to enter the study.

Participants/Inclusion and exclusion criteria
Idiopathic Parkinson's patients, age 30 to 80 years; Idiopathic Parkinson's disease; Not changing the drug regimen, food, and supplements during 8 weeks, who declare their agreement to participate in the clinical trial through a written consent form.

Intervention groups
The intervention group will consume a capsule containing 30 mg of crocin twice a day for 8 weeks. Both groups will receive nutrition education and non-drug solutions for treatment in the form of brochures. The intervention product and placebo will be prepared by Sami Saz Pharmaceutical Company of Mashhad, with the same packaging, shape, taste, and smell.

Main outcome variables
To investigate the use of crocin and its effect on the Movement Disorders Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) (episodes of dyskinesia, tremor, and cognitive disorders) in the patient.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170608034390N12**
Registration date: **2022-12-09, 1401/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-09, 1401/09/18**
Update count: **0**

Registration date
2022-12-09, 1401/09/18

Registrant information

Name
Hadi Esmaily

Name of organization / entity
SBMU

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-22, 1401/09/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the Efficacy of Crocin on Movement Disorders and Neuronal Oxidative Stress of Parkinson's Disease; A Double-blind, Randomized, Placebo-controlled Clinical Trial

Public title

Evaluating the Efficacy of Crocin on Movement Disorders and Neuronal Oxidative Stress of Parkinson's Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic Parkinson's patients Age 30 to 80 years No change in diet, medication and supplements during 8 weeks They declare their agreement to participate in the clinical trial through a written consent form

Exclusion criteria:

Patients with a history of saffron allergy Patients with severe episodes of wearing off Consumers of saffron more than 1 gram per day Taking warfarin, monoamine oxidase inhibitors Pregnant and lactating patients Liver disease Occurrence of urticaria complications; skin itching; Nausea and vomiting and dizziness Patients with severe Hoehn and Yahr stage 5 Parkinson's disease

Age

From **30 years** old to **80 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: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

We will randomly divide the participants into two groups with the same size of 27 participants (54 patients in total), to ensure the equal distribution of patients in the two groups, the block randomization method will be used, and 9 blocks of 6 people in total will be created. Sealed Envelope online software will be used to create random codes. Patients who meet the inclusion criteria receive the code in order and based on the grouping of random blocks, for example, the distribution and coding in the first block is as follows, the first patient Group A, the unique code is ZX6, the second patient Group A, the unique code is GA6, Group B third patient, FR9 code, Group B fourth patient, PP3 code, Group A fifth patient, FR9 code, Group B sixth patient, AE8 code. The number of patients in groups A and B in each block is equal, but the random sequence will be different

Blinding (investigator's opinion)

Triple blinded

Blinding description

After preparing the medicine and placebo, they will be packed in the same box by a clinical laboratory expert who is outside the researchers and will be provided with random codes based on the Excel file extracted from the Sealed Envelope software. The package will be transported to the clinic and the codes will closed till the statistical analysis is performed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of

Street address

Valiasr

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.071

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

Unified Parkinson's Disease Rating Scale (UPDRS)

Timepoint

At the beginning and eight weeks after the start of the study

Method of measurement

Unified Parkinson's Disease Rating Scale (UPDRS) Questionnaire

Secondary outcomes

1

Description
Malondialdehyde reduction in blood (oxidative stress biomarker)
Timepoint
The beginning of the study and the end of the study
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Patients will take an oral capsule containing 30 mg of crocin in the morning and evening for 8 weeks. Granules containing crocin were obtained from Sami Saz Pharmaceutical Company in Mashhad and filled in capsules in the pharmaceutical pilot production laboratory located in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences under GMP conditions. The medicine was filled in capsules and in white polyethylene jars was packed in 60 pieces.
Category
Treatment - Drugs

2

Description
Placebos were filled in the pilot production laboratory of the Faculty of Pharmacy, located in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences, under GMP conditions, in oral capsules with the same color and shape as the study product (intervention group), the capsules were filled and placed in white polyethylene jars. Packed in 60 capsules. Patients will take one in the morning and one in the evening for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital Neurology clinic
Full name of responsible person
Saeed Mohammad Soleymani
Street address
Shahid madani
City
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Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
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info@ehmc.ir

2

Recruitment center
Name of recruitment center
Shohadaye Tajrish Educational Hospital
Full name of responsible person
Saeed Mohammad Soleymani
Street address
Shahdari St, Tajrish Square
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Pr_shohada@sbmu.ac.ir
Web page address
https://shmc.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Deputy of Research and Technology, Shahid Beheshti University of Medical Sciences and Health Services, Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
City
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Tehran
Postal code
1985717443
Phone
+98 21 2243 9781
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi Esmaily

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

Assistant Professor

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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

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

potentially the whole data will be published after participants become unidentified

When the data will become available and for how long

The data will be available 6 months after data publish.

To whom data/document is available

Industrial and Academic Researchers

Under which criteria data/document could be used

To carry out further research

From where data/document is obtainable

Dr. Hadi Esmaily, School of Pharmacy, Shahid Beheshti University of Medical Sciences.

What processes are involved for a request to access data/document

It can be provided by sending a request by email. Email

to the person in charge of the study: Esmaily_hadi@sbmu.ac.ir

Comments