

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the Effects of Crocus Sativus herbal product on Chronic Fatigue Syndrome in Patients with Chronic Obstructive Pulmonary Disease

#### Protocol summary

##### Study aim

Determining the effects of crocus sativus herbal product on the improvement of chronic fatigue syndrome in patients with chronic obstructive pulmonary disease. Determining the effects of crocus sativus herbal product on improving the quality of life in patients with chronic obstructive pulmonary disease.

##### Design

A controlled, parallel groups, randomized, double blinded and phase 3 clinical trial on 70 patients

##### Settings and conduct

This study is conducted on 70 patients referred to Masih Daneshvari hospital clinic. Patients and researchers are blinded to the study groups. Blinding was performed by the drug manufacturing company (Faran Shimi).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for patients: People over 18 years of age with chronic obstructive pulmonary disease and chronic fatigue syndrome (based on IOM criteria) at the same time that they refer to the lung clinic of Masih Daneshvari Hospital. Exclusion criteria for patients: Pregnancy and breastfeeding Rheumatoid diseases and osteoarthritis electrolyte disorders adrenal insufficiency Obstructive sleep apnea disease Patient with acute exacerbation in the last month History of central nervous system disease Taking any sleep-sedative drugs, stimulant drugs, antidepressants, anticoagulant drugs Allergy to saffron or formulation components Having any known neurological and mental illness

##### Intervention groups

Patients in the intervention group received capsules containing 30 mg of dry saffron extract (prepared by Faran Shimi company) twice a day for two months. In the control group, patients use placebo in the same way.

##### Main outcome variables

The effect of crocus sativus on chronic fatigue syndrome in COPD patients using Chronic Respiratory

Questionnaire (CRQ) and Manchester COPD Fatigue Scale (MCFS) questionnaires

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N34**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

##### Registration date

2023-10-09, 1402/07/17

##### Registrant information

##### Name

Farzaneh Dastan

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 270 5933

##### Email address

f\_dastan@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-12, 1402/07/20

##### Expected recruitment end date

2024-10-11, 1403/07/20

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the Effects of Crocus Sativus herbal product on Chronic Fatigue Syndrome in Patients with Chronic Obstructive Pulmonary Disease

**Public title**

Evaluating the effects of saffron on fatigue symptoms in patients with chronic obstructive pulmonary disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

People over 18 years old with chronic obstructive pulmonary disease and chronic fatigue syndrome at the same time

**Exclusion criteria:**

Pregnancy and breastfeeding suffering from Rheumatoid diseases and osteoarthritis Having electrolyte disorders Suffering from adrenal insufficiency Suffering from obstructive sleep apnea disease Suffering from other lung diseases such as asthma, lung fibrosis Patient with acute exacerbation of chronic obstructive pulmonary disease in the last month History of central nervous system disease (stroke, epilepsy, tumor, history of neurosurgery) Taking any sleep-sedative drugs, stimulant drugs, antidepressant and anticoagulant drugs Allergy to saffron or formulation components Having any known Nervous and mental illness

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, block randomization method is used. Thirty five block including 2 patients generated with the help of the online website ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)). In each block, one patient is assigned to the crocus sativus group and one patient to the control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients included to the study are randomized to two groups of drug and control (crocus sativus and placebo) by a randomizer according to the randomization list

taken from [www.sealedenvelope.com](http://www.sealedenvelope.com). The researcher and data analyst only receive the data in code and were not aware of patients' assignments to the two groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee in Research of Pharmacy, Nursing and Midwifery Faculties Shahid Beheshti University

**Street address**

No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1991953381

**Approval date**

2023-05-23, 1402/03/02

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1402.033

**Health conditions studied****1****Description of health condition studied**

Chronic obstructive pulmonary disease

**ICD-10 code**

J44

**ICD-10 code description**

Other chronic obstructive pulmonary disease

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

Investigating the effect of herbal product containing crocus sativus on chronic fatigue syndrome in patients with COPD

**Timepoint**

The beginning of the study, the end of the first month and the end of the second month

**Method of measurement**

Manchester COPD Fatigue Scale (MCFS) and Chronic Respiratory Questionnaire (CRQ) questionnaire

## Secondary outcomes

### 1

#### Description

Investigating the effect of crocus sativus herbal product on the quality of life of patients with chronic obstructive pulmonary disease

#### Timepoint

The beginning of the study, the end of the first and second month

#### Method of measurement

St. George's Respiratory Questionnaire (SGRQ) questionnaire

### 2

#### Description

Investigating the effect of crocus sativus herbal product on the severity of shortness of breath in patients with COPD

#### Timepoint

The beginning of the study, the end of the first and second month

#### Method of measurement

Modified Medical Research Council (mMRC) and Body mass index, airflow Obstruction, Dyspnea, and Exercise capacity (BODE Index) score

## Intervention groups

### 1

#### Description

Intervention group: Patients in the intervention group received capsules containing 30 mg of dry saffron extract (Duralife® prepared by Faran Shimi Company) twice a day for two months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients in the control group received placebo capsules prepared by Faran Shimi Company twice a day for two months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Farzaneh Dastan

##### Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

#### City

Tehran

#### Province

Tehran

#### Postal code

1956944413

#### Phone

+98 21 2712 3000

#### Email

f\_dastan@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

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 23871

##### Email

mpd@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

Reza Mahmoodian

##### Position

Resident

##### Latest degree

Medical doctor  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
19569-44413  
**Phone**  
+98 21 2712 2227  
**Email**  
mahmoodian.reza@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Dastan  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Faculty of Pharmacy, Shahid Beheshti University of  
Medical Sciences, Intersection of Niyayesh Highway,  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Reza Mahmoodian  
**Position**  
Resident  
**Latest degree**

Medical doctor  
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Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran  
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mahmoodian.reza@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

All potential data can be shared after blinding.

### When the data will become available and for how long

Six months after publishing the results

### To whom data/document is available

Researchers working in academic institutions

### Under which criteria data/document could be used

For research purposes and meta-analysis studies

### From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,  
Daar-Abad, Niavaran

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

Official letter to the researchers through Email  
(fzh.dastan@gmail.com)

### Comments