Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Farzaneh Dastan
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Shahid Beheshti University of Medical Sciences
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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). 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. 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
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Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

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Person responsible for updating data

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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