

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of saffron on pulmonary function and serum levels of Interleukin-6 and Tumor Necrosis Factor- α in patients with Chronic Obstructive Pulmonary Disease

Protocol summary

Study aim

Evaluation of the saffron effects on serum levels of interleukin-6 and tumor necrosis factor-alpha in chronic obstructive pulmonary disease (COPD).

Design

A randomized, double-blind with parallel groups in placebo-controlled clinical trial.

Settings and conduct

COPD patients referred to pulmonary clinic of Imam Khomeini Hospital in Ardabil, who fulfilled inclusion criteria, were invited to participate in this study. Demographic data (age, height, weight, body mass index, exacerbation rate, smoking history), MMRC (modified Medical Research Council) dyspnea scale and COPD assessment test (CAT) are completed by patients. Then, spirometry, pulse-oximetry, and 6-minute walk distance tests are administered. Blood sample is drawn for serum IL-6 and TNF- α levels analysis. Coded packets containing saffron and placebo (A or B codes) are randomly assigned by a medical physician to the patients and the control groups. Then, 30 mg saffron tablets and the placebo are prescribed once daily for 12 weeks. After 4 weeks of intervention complete examination and drug side effects are conducted by physician. At the end of the 12th weeks, physical examination, spirometry, pulse-oximetry, CAT questionnaire, 6-minute walk distance test and blood sampling for serum IL-6 and TNF- α levels will be conducted.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COPD patients; Age between 40-85 years; Clinically stable disease in previous 8 weeks; Acceptance of study design by patients. Exclusion Criteria: History of malignancy, Diabetes, Cardiac disease, Chronic inflammatory disease, Liver disease.

Intervention groups

Intervention group: Efficacy of saffron on pulmonary

function and inflammatory markers in Chronic Obstructive Pulmonary Disease. Control group: Receiving placebo in patients with Chronic Obstructive Pulmonary Disease.

Main outcome variables

The level of IL-6, TNF- α , Pulmonary Function Test

General information

Reason for update

Adding variables to the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20110109005579N2**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **1**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

Hassan Ghobadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 45 3325 1401

Email address

h.ghobadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of saffron on pulmonary function and serum levels of Interleukin-6 and Tumor Necrosis Factor- α in patients with Chronic Obstructive Pulmonary Disease

Public title

Saffron effect in Chronic Obstructive Pulmonary Disease (COPD).

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic Obstructive Pulmonary Disease Age between 40-85 Clinically stable disease in previous 8 weeks Acceptance of study design by patients

Exclusion criteria:

Active infectious disease Bronchiectasis Chronic inflammatory diseases Active liver and kidney diseases Cancer patients Cardiac disease (myocardial infarction and unstable angina in previous 6 months) Sensitivity to saffron

Age

From **40 years** old to **85 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be recruited from patients that referred to the pulmonary clinic of Ardabil Imam Khomeini Hospital. Patients will be evaluated and in the case of satisfying inclusion criteria, they will be referred to the clinics nurse. A per-defined list will be utilized for subject's enrollment. The list consists two groups of trial and placebo (each 45 subjects) which was prepared by Excel using Randbetween function. Patients will be allocated in two groups by simple randomization. 45 "A" labeled and 45 "B" labeled sealed envelopes will be used by nurse to provide medicine and placebo to patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, patient care student and outcome

evaluator, person responsible for data collection don't aware from pocket contents.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ardabil University of Medical Sciences Ethic Committe

Street address

Internal Medicine Department, Emam Khomeini Hospital, Shahid Noe-Aghdam Street, Ardabil

City

Ardabil

Province

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Postal code

56196-47531

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.ARUMS.REC.1397.279

2**Ethics committee****Name of ethics committee**

Ardabil University of Medical Sciences Ethic Committe

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Internal Medicine Department, Emam Khomeini Hospital, Shahid Noe-Aghdam Street, Ardabil

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Approval date

2019-11-03, 1398/08/12

Ethics committee reference number

IR.ARUMS.REC.1398.428

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

Chronic obstructive pulmonary disease

ICD-10 code

J44.8

ICD-10 code description

Other specified Chronic Obstructive Pulmonary Disease

Primary outcomes

1

Description

Serum Level of IL-6

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Laboratory

2

Description

Tumor Necrosis factor alpha (TNF- α)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Laboratory

3

Description

Pulmonary Function Test

Timepoint

beginning of study and 12 weeks after intervention

Method of measurement

Laboratory (Spirometry Device)

4

Description

Total oxidant status (TOS)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Laboratory

5

Description

Total antioxidant capacity (TAC)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Laboratory

6

Description

Nuclear factor kappa B (NF- κ B)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Laboratory

Secondary outcomes

1

Description

COPD Assessment Test (CAT)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

CAT Questionnaire, accessible at:

<https://www.catestonline.org>

2

Description

Dyspnea scale: Modified Medical Research Council (MMRC) questionnaire

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Modified Medical Research Council (MMRC) questionnaire

3

Description

Exercise scale: Six Minute Walk Distance (6MWD)

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Six Minute Walk Distance (6MWD) questionnaire

4

Description

Oxygen saturation of arterial blood

Timepoint

Beginning of study and 12 weeks after intervention

Method of measurement

Pulse oximetry

5

Description

Saffron side effects

Timepoint

4 weeks and 12 weeks after intervention

Method of measurement

Record of adverse effect in checklist

Intervention groups

1

Description

"Intervention group:" Patients with Chronic Obstructive Pulmonary Disease will be receive standard treatments based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline and 30mg/day Saffron Tablets for 12 weeks (Produced by: BuAli Institute of Pharmaceutical Sciences, Pharmaceutical Product Development Center, Sina Pharmaceutical Company, Reg. No. 48674).

Category

Treatment - Drugs

2

Description

"Control group:" Patients with Chronic Obstructive Pulmonary Disease will be receive standard treatments

based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline and 30mg/day Saffron Placebo Tablets for 12 weeks (Produced by: BuAli Institute of Pharmaceutical Sciences, Pharmaceutical Product Development Center, Sina Pharmaceutical Company, Reg. No. 48674).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Khomeini Hospital, Ardabil

Full name of responsible person

Hassan Ghobadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Vice-president for research affair

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Hassan Ghobadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonologist

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Hassan Ghobadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

Data of outcome can be shared.

When the data will become available and for how long

Result access after paper publication

To whom data/document is available

Academic researcher

Under which criteria data/document could be used

As a scientific paper

From where data/document is obtainable

Corresponding author, Hassan Ghobadi

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

via email address: h.ghobadi@arums.ac.ir

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

Hassan Ghobadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pulmonologist

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