Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 pockets 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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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
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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
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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-κB)
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 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
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