Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of saffron and herbal formula (based on chamomile) on respiratory symptoms and inflammatory biomarkers of pulmonary chemical veterans in comparison to placebo

Protocol summary

Study aim
Evaluating effectiveness of saffron and herbal formula (based on chamomile) on respiratory symptoms and inflammatory biomarkers of pulmonary chemical veterans in comparison to placebo

Design
Randomized, controlled, phase 3, parallel groups, clinical trial on 160 pulmonary chemical veterans. After stratification based on underlying disease, participants will be divided into 4 groups using block randomization method with random allocation software (SPSS). In Strata 1, Groups 1 and 2 receive herbal syrup or its placebo 10 cc every 12 hours and in strata 2, groups 1 and 2 receive saffron capsule or its placebo 1 capsule every 12 hours.

Settings and conduct
This trial will be held in Tehran Baqiyatallah hospital. After informing the public, volunteers who have inclusion criteria will be divided randomly into 4 groups. They are not aware that they are in intervention group or placebo group. Respiratory symptoms will be evaluated at weeks 0, 4, and 8 and inflammatory markers will be assessed at weeks 0 and 8 and data will be analyzed using SPSS software.

Participants/Inclusion and exclusion criteria
Mustard gas pulmonary chemical veterans aged 40-65 years old

Intervention groups
Strata 1: Group 1: herbal syrup Group 2: herbal placebo
Strata 2: Group 1: saffron capsule Group 2: placebo capsule

Main outcome variables
Dyspnea severity; Cough severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171007036614N4**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **prospective**

Last update: **2023-10-17, 1402/07/25**
Update count: **0**

Registration date
2023-10-17, 1402/07/25

Registrant information

Name
Mohammad Sadegh Adel-Mehraban

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of saffron and herbal formula (based on

chamomile) on respiratory symptoms and inflammatory biomarkers of pulmonary chemical veterans in comparison to placebo

Public title
Effectiveness of saffron and herbal formula on respiratory symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of mustard gas induced lung injury by a pulmonologist Previous asthma Seasonal Allergy Acute respiratory infection Smoking Alcohol consuming
Exclusion criteria:
Uncontrolled hypertension Unwilling to participate
Age
From **40 years** old to **65 years** old
Gender
Male

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are divided into 2 strata. First, patients with underlying disease (diabetes and hypertension) and second, patients without underlying disease. Then patients in each strata randomly divided into 2 groups by the block randomization method perfomed by SPSS software. Strata 1: group 1 receives herbal syrup and group 2 placebo syrup. Strata 2: group 1 saffron capsule and group 2: placebo capsule.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Herbal syrup, saffron capsule, and their placebo will be provided in A or B label by a pharmacist who is not involved in performance of the study. Participants of each strata are not aware that they are in which group (intervention or placebo). Outcomes will be measured by a third party who is not aware about group of participants and type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Baqiyatallah Hospital
Street address
Sheikh bahai St., Molasadra Ave.
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Province
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Postal code
1435916471
Approval date
2023-10-02, 1402/07/10
Ethics committee reference number
IR.BMSU.BAQ.REC.1402.072

Health conditions studied

1

Description of health condition studied
Unspecified injury of lung
ICD-10 code
S27.30
ICD-10 code description
Unspecified injury of lung

Primary outcomes

1

Description
Dyspnea severity
Timepoint
Before treatment and after 4 and 8 weeks
Method of measurement
St George's Respiratory Questionnaire

2

Description
Cough severity
Timepoint
Before treatment and after 4 and 8 weeks
Method of measurement
St George's Respiratory Questionnaire

Secondary outcomes

1

Description
Interleukin 6
Timepoint
Before treatment and 8 weeks
Method of measurement
ELISA

2

Description
Glutathione (GSH)
Timepoint
Before treatment and 8 weeks
Method of measurement
ELISA

3

Description
Malondialdehyde (MDA)
Timepoint
Before treatment and 8 weeks
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group, strata 1: Herbal product formulation (containing chamomile, thyme, licorice, jujube, fig, nettle, mistletoe and hyssop) based on the basic study of Karimi et al. (Efficacy of Persian medicine herbal formulations (capsules and decoction) compared to standard care in patients with COVID) -19, a multicenter open-labeled, randomized, controlled clinical trial) with the difference that in this study, the boiled medicine is given to the patients in the form of syrup and a quarter of the dose used in the previous study. Participants without underlying disease will use 10 cc of syrup every 12 hours. The study period will be 8 weeks. Syrup will be standardized based on total phenol.
Category
Treatment - Drugs

2

Description
Intervention group, strata 2: Participants with underlying disease will take one saffron capsule daily (standardized to 15 mg of crocin per capsule) every 12 hours. The study period will be 8 weeks.
Category
Treatment - Drugs

3

Description
Control group, strata 1: The syrup placebo will be prepared by water, sugar and food coloring completely similar to herbal syrup, and the participants will use 10 cc of syrup every 12 hours for 8 weeks.
Category
Placebo

4

Description
Control group, strata 2: The placebo capsule will be filled with pectin and will look exactly the same as the intervention capsule, and the patients will use 1 capsule every 12 hours for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Mohammad Sadegh Adel-Mehraban
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad Sadegh Adel Mehraban
Position
PhD student
Latest degree
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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
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Gathered data will be analyzed and then published.
When the data will become available and for how long
After publishing study
To whom data/document is available
Everyone (depending on the journal policies)
Under which criteria data/document could be used
Published article will be public.
From where data/document is obtainable
The journal that the paper is published in.
What processes are involved for a request to access data/document
Sending Email to corresponding author.
Comments