

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

###### Phone

+98 31 3624 3214

###### Email address

sadeghadel@gmail.com

##### 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 performed 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.

##### City

Tehran

##### Province

Tehran

##### 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

#### **Street address**

Molasadra St.

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#### **Postal code**

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#### **Phone**

+98 21 8755 4503

#### **Email**

sadeghadel@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Bagheiat-allah University of Medical Sciences

#### **Full name of responsible person**

Hassan Baqeri

#### **Street address**

Molasadra St.

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#### **Email**

h.baqheri82@gmail.com

### **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**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

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**Position**

PhD student

**Latest degree**

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**Other areas of specialty/work**

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

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**Full name of responsible person**

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**Position**

PhD student

**Latest degree**

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Traditional Medicine

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**Postal code**

1417613151

**Phone**

+98 21 8897 4535

**Email**

sadeghadel@gmail.com

**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**