

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Preventive efficacy of dried lime (*Citrus aurantifolia*) in common cold among Hajj pilgrims: A randomized, double-blind placebo-controlled clinical trial

#### Protocol summary

##### Study aim

to evaluate the preventive efficacy of dried lime preparation in common cold among Iranian pilgrims in a randomized, double-blind placebo-controlled clinical trial during Hajj period

##### Design

In this research, 112 eligible patients were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

##### Settings and conduct

Since travel of the Iranian pilgrims to Saudi Arabia last four weeks (two weeks in the city of Mecca and two weeks in the city of Medina), our study was conducted by the present time of pilgrims in these cities. General practitioner visited all patients and enrolled in the trial based on inclusion criteria. Group allocation was concealed by assigning a unique code to each participant. In this study, the participants, the general practitioner who visited the patients, the data collection authorities, those who evaluate the outcome, those who prepare the draft article, and Data Safety and Monitoring Committee to assign study groups Were blind. But the main investigator was not blind to the study groups.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: All men and women aged 35 to 80 years participating in the Hajj who agree with the aim of the study exclusion criteria: participants who have asthma participants who have a chronic obstructive pulmonary disease participants who have uncontrolled heart diseases participants who have heart failure participants who have a hepatic and renal failure participants who have a history of previous chest surgery.

##### Intervention groups

Intervention group: Patients in drug group received dried

lime capsules, 500 mg in a single dose per day for four weak. Test drug consisting of *Citrus aurantifolia* and sugar. The dried fruit of *Citrus aurantifolia* was purchased from the green market in Shiraz (Iran) and was authenticated by a botanist and was kept at the Herbarium of the Faculty of Pharmacy, Shiraz University of Medicinal Sciences, Shiraz, Iran. 500 milligram of the milled powder of dried fruit of *Citrus aurantifolia* and 50 milligrams of sugar as filler filled into a capsule. Control group: In the placebo group, patients received placebo capsules with the same method.(a single dose per day for four weak) Placebo capsule, consisting of 550 milligrams of flour with identical size and shape to test drug.

##### Main outcome variables

the severity of a cough, rhinorrhea, fever, and body pain that ranged from 0-5 scores (without manifestation to severe symptom).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170704034897N2**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **retrospective**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

##### Registration date

2018-01-30, 1396/11/10

##### Registrant information

##### Name

Seyed Hossein Owji

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

**Phone**

+98 71 3624 7985

**Email address**

owji\_h@sums.ac.ir

**Recruitment status**

Recruitment complete

**Funding source**

**Expected recruitment start date**

2014-09-10, 1393/06/19

**Expected recruitment end date**

2014-09-20, 1393/06/29

**Actual recruitment start date**

2014-09-10, 1393/06/19

**Actual recruitment end date**

2014-09-20, 1393/06/29

**Trial completion date**

empty

**Scientific title**

Preventive efficacy of dried lime (Citrus aurantifolia) in common cold among Hajj pilgrims: A randomized, double-blind placebo-controlled clinical trial

**Public title**

Efficacy of dried lime in common cold among Hajj pilgrims

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All men and women aged 35 to 80 years participating in the Hajj who agree with the aim of the study

**Exclusion criteria:**

participants who have asthma participants who have a chronic obstructive pulmonary disease participants who have uncontrolled heart diseases participants who have heart failure participants who have a hepatic and renal failure participants who have a history of previous chest surgery.

**Age**

From **35 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **126**

Actual sample size reached: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

One hundred and twelve eligible patients were

randomized into two parallel groups. A statistician generated a randomized list by using NCSS (statistical software) with simple block randomization method. All patients visited by a general practitioner and enrolled participants in the trial were assigned to drug or placebo group, according to randomization list.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the participants, the general practitioner who visited the patients, the data collection authorities, those who evaluate the outcome, and Data Safety and Monitoring Committee to assign study groups Were blind. But the main investigator was not blind to the study groups. Also, the author of the article had been blind at the end of the work too.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shiraz University of medical sciences

**Street address**

Shiraz University of medical sciences, Zand street, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2014-05-01, 1393/02/11

**Ethics committee reference number**

EC2798

**Health conditions studied**

**1**

**Description of health condition studied**

common cold

**ICD-10 code**

J00

**ICD-10 code description**

Acute nasopharyngitis [common cold]

**Primary outcomes**

## 1

### **Description**

the severity of a cough

### **Timepoint**

First , second, third and fourth week after intervention

### **Method of measurement**

By self-administered questionnaire that ranged from 0-5 scores (without symptoms to severe symptoms)

## 2

### **Description**

the severity of rhinorrhea

### **Timepoint**

First , second, third and fourth week after intervention

### **Method of measurement**

By self-administered questionnaire that ranged from 0-5 scores (without symptoms to severe symptoms)

## 3

### **Description**

the severity of fever

### **Timepoint**

First , second, third and fourth week after intervention

### **Method of measurement**

By self-administered questionnaire that ranged from 0-5 scores (without symptoms to severe symptoms)

## 4

### **Description**

the severity of body pain

### **Timepoint**

First , second, third and fourth week after intervention

### **Method of measurement**

By self-administered questionnaire that ranged from 0-5 scores (without symptoms to severe symptoms)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Patients in drug group received dried lime capsules, 500 mg in a single dose per day for four weak. Test drug consisting of Citrus aurantifolia and sugar. The dried fruit of Citrus aurantifolia was purchased from the green market in Shiraz (Iran) and was authenticated by a botanist and was kept at the Herbarium of the Faculty of Pharmacy, Shiraz University of Medicinal Sciences, Shiraz, Iran. 500 milligram of the milled powder of dried fruit of Citrus aurantifolia and 50 milligrams of sugar as filler filled into a capsule.

#### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: In the placebo group, patients received placebo capsules with the same method.(a single dose per day for four weak) Placebo capsule, consisting of 550 milligrams of flour with identical size and shape to test drug.

### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Iranian Hajj and Pilgrimage Medical Center in Mecca and Medina

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

Dr. Mehdi Pasalr

##### **Street address**

Shiraz Medical School, Imam Hossein Square, Shiraz, Iran

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##### **Postal code**

7134845794

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+98 71 3233 8476

##### **Email**

pasalar@sums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shiraz University of Medical Sciences

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

Dr. Seyed Basir Hashemi

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hashemib@yahoo.com

##### **Web page address**

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes  
**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Seyed Hossein Owji  
**Position**  
Medical Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Internal Medicine  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
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**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Part of the individual information of the participants, such as information on the main outcome of the data in the study, is the possibility of sharing. This information includes some of the demographic characteristics and

data related to the severity of a cough, rhinorrhea, body pain and fever.

**When the data will become available and for how long**

Start the access period 6 months after publishing the results for 1 month

**To whom data/document is available**

Only for researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Only a descriptive survey of data is allowed.

**From where data/document is obtainable**

By sending an email to the scientific responsible of the study, Dr. Pasalar, at the following address:  
pasalar@sums.ac.ir

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

After the request has been sent, it will be answered within a maximum of 2 months.

**Comments**