Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Preventive efficacy of dried lime (Citrus aurantifulia) 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 Saftey 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 aurantifulia and sugar. The dried fruit of Citrus aurantifulia 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 aurantifulia 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

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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 aurantifulia) 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 Saftey 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 aurantifulia and sugar. The dried fruit of Citrus aurantifulia 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 aurantifulia 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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7134845794
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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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Phone
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Email
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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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mehdi Pasalar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Contact

Name of organization / entity

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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

Internal Medicine

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owji_h@sums.ac.ir

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