

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Managemnt of adult asthma:a randomized-double blind -placebo controlled-parallel trial of Ziziphus spina christi leaf extract

#### Protocol summary

##### Summary

Asthma is characterized by frequent episodes of shortness of breath, wheezing and coughing. The management of asthma is based on avoidance of the trigger factors, oral and inhaled medications albeit some herbals. Ziziphus spina-christi(L.) used for bronchitis and coughing. It had never been investigated in clinical trials to evaluate the efficacy in asthmatic patients. The aim of this study is to evaluate the effect of Z.spina-christi leaf extract in adult asthmatic patients. A randomized, double blind, placebo control, parallel clinical trial to compare the extract with placebo in moderate to severe asthmatic patients. 50 previously diagnosed asthmatic patients and stable on current therapies were randomly divided in 2 arms. Placebo group and extract group; 25 patients in each arm who are on regular repeat medications plus placebo or extract and were used twice a day on alternate days as a steam inhalation. The Pulmonary Function Test (PFT) and St George's questionnaire were completed at base line. Follow up weekly for a period of 2 month.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311173106N14**

Registration date: **2014-01-22, 1392/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-01-22, 1392/11/02

##### Registrant information

##### Name

Farshad Hashemian

##### Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2260 0037

##### Email address

hashemian.f@iaups.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

1- Pharmaceutical Sciences branch of Islamic Azad University, 2- investigators financial sources

##### Expected recruitment start date

2012-09-15, 1391/06/25

##### Expected recruitment end date

2013-09-01, 1392/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Managemnt of adult asthma:a randomized-double blind - placebo controlled-parallel trial of Ziziphus spina christi leaf extract

##### Public title

Study of the effect of inhaled extract of ziziphus spina christi leaf in asthmatic patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: history of asthma diagnosis; the patients who signature satisfaction letter of ethical committee; stable on current therapy. Exclusion criteria: another respiratory complications; lung cancer; acute

infection and exacerbation; pregnancy; non agreements and non cooperatives.

### Age

From **18 years** old to **70 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Islamic azad university-pharmaceutical science branch

##### Street address

N99,Yasaman alley,Yakhchal st, shariati st,

##### City

Tehran

##### Postal code

##### Approval date

2012-08-30, 1391/06/09

##### Ethics committee reference number

11849

## Health conditions studied

### 1

#### Description of health condition studied

Asthma

#### ICD-10 code

J45.8

#### ICD-10 code description

Mixed asthma

## Primary outcomes

### 1

#### Description

FEV1

#### Timepoint

After 1month and after 2 months

#### Method of measurement

By liter and by spirometry machinery

## Secondary outcomes

### 1

#### Description

Assessment of quality of life

#### Timepoint

After 1 month and 2 months

#### Method of measurement

ST George respiratory questionnaire

## Intervention groups

### 1

#### Description

The patients who are on regular repeat medication,had used Ziziphus spina christi leaf extract by the route of steam inhalation,2o drops of extract in half of liter of water for 15 minutes twice a day on alternate days for 2 month.

#### Category

Treatment - Drugs

### 2

#### Description

The patients who are on regular repeat medication,had used placebo by the route of steam inhalation,2o drops of extract in half of liter of water for 15 minutes twice a day on alternate days for 2 month.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bouali hospital

##### Full name of responsible person

##### Street address

Damavand street, Emam hosein square

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Islamic Azad university-pharmaceutical science  
branch

**Full name of responsible person**

Dr. Mehdi Rajabi

**Street address**

No.99,Yasaman alley,Yakhchal st.,Shariati st.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad university-pharmaceutical science branch

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad university -pharmaceutical science

branch

**Full name of responsible person**

Dr. Mehdi Rajabi

**Position**

PhD-Assistant professor

**Other areas of specialty/work**

**Street address**

Yasaman alley, yakhchal st, shariati st,

**City**

Tehran

**Postal code**

**Phone**

+98 21 2260 9043

**Fax**

**Email**

mehdirj@aol.co.uk

**Web page address**

**Person responsible for updating data**

**Contact**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*