# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 asthmetic 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

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**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*