

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

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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

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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