

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Benefit of Oral Platanus and Rosemary extract on clinical, physiological and biological improvement of resistant asthma, a double blind randomized placebo controlled active comparator study on asthmatic resistant to traditional treatment.

Protocol summary

Summary

Objectives: Platanus and rosemary extract were routinely used in Iranian traditional medicine for asthma. They proved to be safe and without complication. The objective of this study was to determine their effect on treatment of resistant asthma. Design: Prospective randomized controlled clinical trial (active comparator study) Setting and conduct: A pulmonary subspecialty clinic Participants including major eligibility criteria: Thirty asthmatic subjects whom at least three drugs for treatment for asthma was not effective to control asthma will be enrolled in this clinical trial. Smokers and subjects suffering from other underlying diseases such as infection will be excluded from study. The subjects will be randomly divided into two groups which for one of them platanus extract plus placebo will be administered and the other will be consumed rosemary extract plus placebo. Intervention: After randomization eligible subjects will receive one plant extract (Platanus or Rosemary). Independent pharmacists dispensed either Platanus or Rosemary according to a computer generated randomization list. Each extract plus placebo will be consumed for one month, after this period they will be evaluated for main parameters and they will receive placebo for wash out. After one month, they will receive another extract plus placebo and again they will experience one month wash out period. At the last month, they will receive both drugs. Main outcome measures (variables): pulmonary clinical findings, spirometry, Exhaled Nitric Oxide (FENO) and asthma control test (ACT).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107312695N2**

Registration date: **2013-05-13, 1392/02/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-13, 1392/02/23

Registrant information

Name

Majid Mirsadraee

Name of organization / entity

Islamic Azad University- Mashhad branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research- Islamic Azad University- Mashhad Branch

Expected recruitment start date

2013-03-06, 1391/12/16

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Benefit of Oral Platanus and Rosemary extract on clinical, physiological and biological improvement of resistant asthma, a double blind randomized placebo controlled active comparator study on asthmatic resistant to traditional treatment.

Public title

Benefit of platanus and Rosemary extract on treatment of resistant asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Resistant asthma to Inhaled corticosteroid, long acting beta 2 agonist, antileukotrien and theophyllin Exclusion criteria: 1- Respiratory infection 2- Fair Treatment with controller drugs 3- Not cooperative with project 4- congestive heart failure 5- Gastroesophageal reflux 6- Rhinosinusitis, 7- pregnancy 8- smoking 9- non asthmatic other lung disease and non pulmonary disease

Age

From **12 years** old to **91 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

All recruited asthmatic subjects will randomly divided to two groups of herbal extract by computer generated randomization list. Both groups contain one true herbal drug (Rosemary or Platanus) and one placebo. The physician and pharmacist are blind to the exact herbal drug which the subject will be started with (Rosemary or Platanus). The Platanus, Rosemary and their placebos were in bottle form and identical in appearance. They were prepacked in bottles and consecutively numbered for each patient according to the randomization schedule which is not introduced to the physician and pharmacist.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Medical school Islamic Azad University- Mashhad branch

Street address

Shahin Far Building- Sarab Street- Azadi street

City

Mashhad

Postal code

9178673799

Approval date

2011-04-08, 1390/01/19

Ethics committee reference number

A34-18

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J459

ICD-10 code description

Asthma, unspecified

Primary outcomes

1

Description

FEV1

Timepoint

before treatment and one month after treatment

Method of measurement

spirometry superspiro, Micromedical company, England

2

Description

Exhaled Nitric oxide (FENO)

Timepoint

before treatment and one month after treatment

Method of measurement

Chemiluminescence instrument, No Breath, Bedford company, England

3

Description

ACT Questionnaire

Timepoint

before treatment and one month after treatment

Method of measurement

Validated Asthma control test Questionnaire

Secondary outcomes

1

Description

IL-17

Timepoint

Before treatment and One month after treatment

Method of measurement

ELIZA- Qiagen company Tehran Iran

2

Description

INF- Gamma

Timepoint

Before treatment and One month after treatment

Method of measurement

ELIZA- Qiagen company Tehran Iran

Intervention groups

1

Description

Starting the trial: As mentioned above all symptomatic asthmatic subjects whom were resistant to treatment with inhaled corticosteroids, Salmeterol, Montelukast and theophylline will be entered in this study. The subjects will continue their previous drugs after that they will be randomly divided in two groups to consume two new herbal drugs. One group will receive platanus extract and placebo in addition to previous drugs and second group will receive Rosemary extract and placebo. Rosemary and Platanus extract has produced by Birjand herbal company and served as liquid which will be drunk (50 CC three times a day). After one month the outcome variables will be evaluated. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedford Medical instruments, England). Subjects whom showed complete improving or side effects of extract will be exited from study. Then both groups will receive placebo with similar shape to previous drugs for one month in order to wash out previous drugs.

Category

Treatment - Drugs

2

Description

Second phase: Subjects will be evaluated for primary outcomes. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedford Medical instruments, England). Subjects whom showed complete improving or side effects of extract will be exited from study. At the third month the groups will be changed and they will use other extract.

At the beginning of fourth month primary outcomes will be evaluated as mentioned above and then both groups will receive placebo again for wash out.

Category

Treatment - Drugs

3

Description

Third (last) phase: In the last month (fifth month) both groups will receive both extracts and trial will be finished with evaluation of outcome parameters for last time. Outcome parameters will be evaluated before and after of this phase. Evaluations consist of clinical evaluation as like as symptoms (cough and dyspnea) and sign (wheeze) and clinical improvement of asthma by validated ACT (Asthma control test) questionnaire; and paraclinical tests such as spirometry (Superspiro, Micromedical instruments, England) and FENO (No Breath, Bedford Medical instruments, England).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical school Islamic Azad University- Mashhad branch

Full name of responsible person

Mojtaba Meshkat

Street address

Shahin Far building, Sarab street, Azadi Avenue

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University- Mashhad Branch

Full name of responsible person

Mojtaba Meshkat

Street address

Shahin Far building, Sarab Street, Azadi avenue

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Islamic Azad University- Mashhad 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

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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