Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The preventive effect of aqueous – alcoholic extract of Zataria multiflora and carvacrol on asthma disease

Protocol summary

Summary

Objectives: determine the effect of hydro-alcoholic extract of Zataria multiflora Boiss and carvacrol on treatment (prevention) of asthma. Design: Randomized, double-blind, controlled with placebo, phase II trial Setting and conduct: In this study, sixty patients with moderate to severe asthma were selected and treated for two months in four groups including: treated patients with hydro-alcoholic extract (in two doses five and ten milligrams per kilogram per day), patients receiving carvacrol (one mg per kg per day) and patients receiving placebo. Major Inclusion and Exclusion criteria: Inclusion criteria including; the diagnosis of asthma according to the World Health Organization criteria for the diagnosis and management of asthma (GINA), the willingness of patients to participate in the project. Exclusion criteria; intolerance of Zataria multiflora Boiss side effects (nausea, vomiting, diarrhea). Intervention: Prescription of Zataria multiflora Boiss syrup and carvacrol for two months to asthma patients. main outcome measures (variables): Measurement of pulmonary function tests, blood cells, inflammatory mediators in serum such as hsCRP, IL-10, IL-4, IFN-ɣ and gene expression of IL-10, IL-4, IFN-ɣ in peripheral blood lymphocytes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101519546N1**
Registration date: **2016-11-26, 1395/09/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-11-26, 1395/09/06

Registrant information

Name
Azam Alavinezhad
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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+98 51 3800 2217
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alavina901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The preventive effect of aqueous – alcoholic extract of Zataria multiflora and carvacrol on asthma disease

Public title

The effect of zataria multiflora boiss on symptoms of asthmatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of asthma, according to World Health Organization criteria, guidelines on diagnosis and management of asthma (GINA), patient

willingness to participate in the project. exclusion criteria: the existence of systemic diseases, Taking other medicines with antioxidant properties, taking any herbal thyme intolerance side effects (nausea, vomiting, diarrhea, etc.), inflammatory disease, gestational, age below 12 years

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

2

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Ghorshi beelding, Daneshgah street

City
Mashhad

Postal code

Approval date
2013-06-22, 1392/04/01

Ethics committee reference number
IR.MUMS.REC.1392.91

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
Volume and lung capacity

Timepoint
Baseline, the end of First and second month

Method of measurement
Spirometry

2

Description
Serum cytokines

Timepoint
zero and sixty days

Method of measurement
ELAISA

3

Description
Cells blood

Timepoint
zero, thirty and sixty days

Method of measurement
Auto analyzer

4

Description
Gen expression

Timepoint
zero and sixty days

Method of measurement
Real time PCR

Secondary outcomes

empty

Intervention groups

1

Description
Control group: placebo (5 ml syrup orally three times daily)
Category
Treatment - Drugs

2

Description
Intervention group 1: Zataria multiflora Boiss syrup (5 mg milligrams per kilogram daily)
Category
Treatment - Drugs

3

Description
Intervention group 2: Zataria multiflora Boiss syrup (10 milligrams per kilogram daily)
Category
Treatment - Drugs

4

Description
Intervention group 3: Capsule of active ingredient (carvacrol 1.2 milligrams per kilogram daily)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Fariba Rezaei talab
Street address
Imam Reza Hospital, Special clinic
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Daneshgah Avenue, Building Qureshi
City
Mashhad
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, Mashhad University of Medical Sciences
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
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohammad hossein Boskabady
Position
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Neurogenic Inflammation Research Centre and Dept. of Physiology, School of Medicine, Mashhad Univers
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Person responsible for updating data

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Physiology PhD candidate

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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