

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 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- $\gamma$  and gene expression of IL-10, IL-4, IFN- $\gamma$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2217

##### Email address

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

Respiratory Physiology PhD

#### Other areas of specialty/work

#### Street address

Department of Physiology, Faculty of Medicine, Ferdowsi University campus, Azadi Square

#### City

Mashhad

#### Postal code

#### Phone

+98 51 3800 2228

#### Fax

#### Email

boskabady@ums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Neurogenic Inflammation Research Centre and Dept. of Physiology, School of Medicine, Mashhad University

#### Full name of responsible person

Mohammad hossein Boskabady

#### Position

Respiratory Physiology PhD

#### Other areas of specialty/work

#### Street address

Department of Physiology, Faculty of Medicine, Ferdowsi University campus, Azadi Square

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Azam Alavinezhad

**Position**

Physiology PhD candidate

**Other areas of specialty/work**

**Street address**

Department of Physiology, Faculty of Medicine,  
Ferdowsi University campus, Azadi Square

**City**

Mashhad

**Postal code**

**Phone**

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**Fax**

**Email**

alavina901@mums.ac.ir

**Web page address**

## 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*