

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of hydro - alcoholic extracts of Zataria multiflora on patients with chronic obstructive pulmonary disease

#### Protocol summary

##### Summary

Objective: The effect of hydro - alcoholic extracts of Zataria multiflora on patients with chronic obstructive pulmonary disease Study design: Randomize, Double blind, control with placebo, second phase of clinical trial Method: In this study, sixty COPD patients were randomly divided into three groups (each group of twenty people). In the first group five mg/kg of hydro - alcoholic extracts of Zataria multiflora, in the second group ten mg/kg of hydro - alcoholic extracts of Zataria multiflora and in the third group placebo daily as oral syrup in three servings for two month will be prescribed. Blood and sputum samples of patients collected at baseline, one month after the start and end of the two months. Main conditions of entry and departure of participants: Inclusion criteria: Diagnosis of chronic obstructive pulmonary disease based on spirometry test and clinical symptoms Exclusion criteria: Having other lung diseases, cardiovascular diseases, chronic inflammatory diseases, acute infections, malignancies, autoimmune diseases and immunodeficiency Interventions: five mg/kg of hydro - alcoholic extracts of Zataria multiflora, ten mg/kg of hydro - alcoholic extracts of Zataria multiflora and also placebo Main outcome variables: The evaluation of clinical symptoms, wheezing rate by chest auscultation, measurement of lung function tests, measurement of inflammatory mediators in serum and sputum

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112729191N2**

Registration date: **2017-01-07, 1395/10/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-07, 1395/10/18

##### Registrant information

###### Name

Vahideh Ghorani Sirjani

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 8565

###### Email address

ghoranisv921@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of hydro - alcoholic extracts of Zataria multiflora on patients with chronic obstructive pulmonary disease

##### Public title

The effect of Zataria in the treatment of chronic obstructive pulmonary disease

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of chronic obstructive pulmonary disease based on spirometry test; clinical symptoms  
Exclusion criteria: Having other lung diseases; cardiovascular diseases; chronic inflammatory diseases; acute infections; malignancies; autoimmune diseases; immunodeficiency

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## 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

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue

##### City

Mashhad

##### Postal code

1394491388

#### Approval date

2016-01-16, 1394/10/26

#### Ethics committee reference number

IR.MUMS.REC.1394.610

## Health conditions studied

### 1

#### Description of health condition studied

Chronic obstructive pulmonary disease

#### ICD-10 code

J44

#### ICD-10 code description

Other chronic obstructive pulmonary disease

## Primary outcomes

### 1

#### Description

Evaluation of clinical symptoms including cough, breathlessness, wheeze

#### Timepoint

Before the intervention, one month after the start of intervention and the end of two months

#### Method of measurement

Standard questionnaire

### 2

#### Description

Wheezing rate

#### Timepoint

Before the intervention, one month after the start of intervention and the end of two months

#### Method of measurement

Chest auscultation

### 3

#### Description

Lung function tests

#### Timepoint

Before the intervention, one month after the start of intervention and the end of two months

#### Method of measurement

Spirometry

### 4

#### Description

Inflammatory mediators in blood serum and sputum

#### Timepoint

Before the intervention, one month after the start of intervention and the end of two months

#### Method of measurement

Standard kits

## Secondary outcomes

### 1

#### Description

-

#### Timepoint

-

## Method of measurement

-

## Intervention groups

### 1

#### Description

Hydro – alcoholic extracts of Zataria multiflora, 5 mg/kg daily as oral syrup (made by the Faculty of Pharmacy, Mashhad University of Medical Sciences), three times a day for two months

#### Category

Treatment - Drugs

### 2

#### Description

Hydro – alcoholic extracts of Zataria multiflora, 10 mg/kg daily as oral syrup (made by the Faculty of Pharmacy, Mashhad University of Medical Sciences), three times a day for two months

#### Category

Treatment - Drugs

### 3

#### Description

Placebo daily as oral syrup (made by the Faculty of Pharmacy, Mashhad University of Medical Sciences), three times a day for two months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Vahideh Ghorani Sirjani

##### Street address

Emam Reza Hospital, Emam Reza square, Doktora intersection

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor of Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Department of Pharmaceutics and Nanotechnology, Faculty of Pharmacy, Ferdowsi University campus,

Azadi square

##### 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 of 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

Vahideh Ghorani Sirjani

##### Position

Pharmaceutical sciences PhD student

##### Other areas of specialty/work

##### Street address

Department of Physiology, School of Medicine, Ferdowsi University campus, Azadi square

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9177948564

##### Phone

+98 51 3882 8888

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##### Email

Ghoranisv921@mums.ac.ir

##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Hossein Boskabady

##### Position

MD, PhD, Physiology

##### Other areas of specialty/work

**Street address**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Vahideh Ghorani Sirjani

**Position**

Pharmaceutical sciences PhD student

**Other areas of specialty/work****Street address**

Department of Physiology, School of Medicine,  
Ferdowsi University campus, Azadi square

**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*