

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of aqueous-alcoholic extracts of *Zataria multiflora* and carvacrol on respiratory symptoms, pulmonary function tests and serum inflammatory mediators in chemical war victims

#### Protocol summary

##### Summary

Aims: Evaluations of respiratory symptoms, chest wheezing, pulmonary function test and serum inflammatory mediators level will measure at baseline, one month and 2 months after treatment. Design of study: In this study 80 patients with pulmonary complication due to sulfur mustard (SM) will randomly divided to four groups including: 1, treated with aqueous-alcoholic extracts 1.5 mg/kg, group 2 treated with aqueous-alcoholic extracts 3 mg/kg, group 3 treated with carvacrol 0.42 mg/kg and group 4 treated with placebo. Methods: All drugs will prescript three times daily (5ml) as syrup for 2 months. Inclusion criteria: The patients exposed to sulfur mustard. Exclusion criteria: The patients should not have any cardiovascular disorders. Respiratory symptoms and pulmonary function test (Primary outcome) serum inflammatory mediators level (Secondary outcome) will be measured as baseline, one month and 2 months after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014031617020N1**

Registration date: **2016-03-04, 1394/12/14**

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

Last update:

Update count: **0**

##### Registration date

2016-03-04, 1394/12/14

##### Registrant information

###### Name

Mohammad Reza Khazdair

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 8888

###### Email address

khazdairmr921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Pharmaceutical research center

##### Expected recruitment start date

2015-07-29, 1394/05/07

##### Expected recruitment end date

2016-10-31, 1395/08/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of aqueous-alcoholic extracts of *Zataria multiflora* and carvacrol on respiratory symptoms, pulmonary function tests and serum inflammatory mediators in chemical war victims

##### Public title

Effect of (aqueous-alcoholic) extracts of *Zataria multiflora* and carvacrol on symptoms, and respiratory function on chemical war victims

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: The patients exposed to sulfur mustard. Exclusion criteria: The patients should not have any cardiovascular disorders

**Age**

From **45 years** old to **80 years** old

**Gender**

Male

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**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**

Mashhad University of Medical Sciences

**Street address**

Vice chancellor of Research, Ghorshi Bilding,  
Daneshgah street, Mashhad, Iran

**City**

Mashhad

**Postal code****Approval date**

2014-07-12, 1393/04/21

**Ethics committee reference number**

920537

**Health conditions studied****1****Description of health condition studied**

Chemical war victims with respiratory symptoms

**ICD-10 code**

J68.4

**ICD-10 code description**

Chronic respiratory conditions due to chemicals, gases,  
fumes and vapours

**Primary outcomes****1****Description**

Respiratory symptoms

**Timepoint**

Baseline, one month and 2 months after treatment

**Method of measurement**

Check list and examination

**2****Description**

Pulmonary function test

**Timepoint**

Baseline, one month and 2 months after treatment

**Method of measurement**

Spirometry

**Secondary outcomes****1****Description**

Serum inflammatory mediators level

**Timepoint**

Baseline, one month and 2 months after treatment.

**Method of measurement**

By elisa kits

**Intervention groups****1****Description**

Group 3: Patients treated with carvacrol 0.42 mg/kg  
three time daily for 2 months

**Category**

Treatment - Drugs

**2****Description**

Group 4: Patients treated with placebo three time daily  
for 2 months

**Category**

Treatment - Drugs

**3****Description**

Group 1: Patients treated with aqueous-alcoholic extracts  
1.5 mg/kg three time daily for 2 months

**Category**

Treatment - Drugs

**4****Description**

Group 2: Patients treated with aqueous-alcoholic extracts  
3 mg/kg three time daily for 2 months

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Clinic, Imam Reza Hospital, Department of Physiology and toxicology research center

**Full name of responsible person**

Mohammad Hossein Boskabady

**Street address**

Department of Physiology, Medical School, MUMS, Mashhad 9177948564, IR Iran

**City**

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of medical Sciences

**Full name of responsible person**

Mohammad Hossein Boskabady

**Street address**

Department of Physiology, Medical School, MUMS, Mashhad 9177948564, IR Iran

**City**

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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**

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 Reza Khazdair

**Position**

PhD student

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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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*