

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

Mashhad

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

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

Azadi Square- Campus of University, School of Medicine

City

Mashhad

Postal code**Phone**

+51 38002216

Fax**Email**

Khazdeirmr921@mums.ac.ir; M.khazdair@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Hossein Boskabady

Position

PhD

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

Department of Physiology, Medical School, Mashhad University of Medical Sciences, Mashhad 9177948564, IR Iran

City

Mashhad

Postal code

9177948564

Phone

+51 38002228

Fax**Email**

boskabadyhm@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Reza Khazdair

Position

PhD student

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

Department of Physiology, Medical School, Mashhad University of Medical Science, Mashhad

City

Mashhad

Postal code**Phone**

+51 38002216

Fax**Email**

Khazdeirmr921@mums.ac.ir; M.khazdair@yahoo.com

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