Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

To investigate anti-inflammatory and anti oxidative stress effects of Curcumin on sulfur mustard-induced lung complications in Iranian veterans

Protocol summary

Summary

Objectives:We will investigate anti-inflammatory and anti oxidative stress effects of curcumin on patients with sulfur mustard-induced lung complications and the efficacy of curcumin in the alleviation of SM-induced chronic obstructive pulmonary symptoms. Study population and Intervention: A total of eighty non-smoker male Iranian veterans (38–62 years) will be randomised to receive either curcumin (1 g/d, n 20) or placebo (n 20) for 8 weeks. Curcumin will be administered for the patients in the form of C3 Complex capsules containing 500 mg curcuminoids and 5mg Bioperine. Placebo capsules containspiperine (5 mg) and are mached in shape, size and dose. Study duration and expected results: It is designed to assess pulmonary function tests and serum levels of a panel of markers: Interleukin-8, interleukin-4, interleukin-13 , monocyte chemoattractant protein-1 ,and Tumor Necrosis Factor-alpha, Immunoglobulin G and Immunoglobulin I, High density lipoprotein, Low density lipoprotein,total cholesterol, lipoprotein(a), triglyceride, and activities of antioxidant enzymes including catalase, super oxide dismutase, and malondialdehyde and homocysteine, at baseline and at the end of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052817888N1**
Registration date: **2015-02-23, 1393/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

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Zahra Khabjavid
Name of organization / entity
Mashhad University Of Medical Sciences ,Faculty Of Medicine, Department Of Biochemistry
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Chemical Injuries Research Center of Baqiyatallah University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate anti-inflammatory and anti oxidative stress effects of Curcumin on sulfur mustard-induced lung complications in Iranian veterans

Public title

To investigate anti-inflammatory and anti oxidative stress effects of Curcumin on sulfur mustard-induced lung complications in Iranian veterans

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Chemical injuries resulting from mustard gas with pulmonary complications, according to medical records at three levels of severity (mild, moderate, severe) according to PFTs results Exclusion criteria: History of allergy to herbal medicine; The need for hospitalization due to the severity of the disease; Taking any antioxidant supplements (vitamin C, E or selenium) at least two weeks before participating in the project ; Contact with a chemical gas in a business environment; smoking .
Age
From **25 years** old to **60 years** old
Gender
Male

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Baghiatallah University of Medical Sciences
Street address
Molla Sadra Str - Tehran
City
Tehran
Postal code
Approval date
2011-12-01, 1390/09/10
Ethics committee reference number
6702/3/340/س

Health conditions studied

1

Description of health condition studied
Lung complications of Sulfur Mustard
ICD-10 code
T97
ICD-10 code description
عوارض واثرات سمی ترکیبات با منابع غیر دارویی

Primary outcomes

1

Description
FEV1
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
spirometery test

2

Description
FVC
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
spirometery test

3

Description
FEV1/FVC
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
spirometery test

4

Description
IL-4
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

5

Description
IL-8
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

6

Description
IL-13
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

7

Description
TNF-α
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

8

Description
MCP-1
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

9

Description
LDL
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

10

Description
HDL
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

11

Description
Total Cholestrol
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

12

Description
TG
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

13

Description
Lp[a]
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

14

Description
SOD
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

15

Description
MDA
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

16

Description
CAT
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

17

Description
IgE
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

18

Description
IgG
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

19

Description
H-Cys
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Serum analysis

20

Description
Weight
Timepoint
Pre- trial -Pre- trial – 2 month later
Method of measurement
Kg

Secondary outcomes

empty

Intervention groups

1

Description
Patients: Curcumin will be administrated for the patients(N=20) in the form of C3 Complex capsules (500mg) twice a day, 1 capsule each 12 hours.
Category
Treatment - Drugs

2

Description
Controls:Placebo capsules will be used for the control group (N=20) containes piperine5 mg (500mg) , twice a day, 1 capsule each 12 hours. Placebo capsules are mached in shape and size with curcumin capsules.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital- Chemical Injuries Research Center
Full name of responsible person
Zahra khabjavid
Street address
N.679, Cheshmeh Alley, Nastaran St., Hasan Abad, Karaj, Alborz, Iran
City
Karaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University Of Medical Sciences ,Faculty Of Medicin
Full name of responsible person
Dr. Tavakol Afshari
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Azadi Sq., Research centee, Faculty Of Medicin, Mashhad University Of Medical Sciences, Mashhad, Khorasan Razavi, 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 ,Faculty Of Medicin
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Chemical Injuries Research Center of Baqiyatallah University of Medical Sciences
Full name of responsible person
Dr.YunesPanahi
Street address
Chemical Injuries Research Center of Baqiyatallah, Baqiyatallah University of Medical Sciences, MollaSadra St., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Chemical Injuries Research Center of Baqiyatallah University of Medical Sciences
Proportion provided by this source
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 ,Faculty Of Medicin, Department Of Biochemistry
Full name of responsible person
Zahra Khabjavid
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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