Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Atrovastatin on inflammatory markers in sulfur mutsard gas induced chronic bronchitis

Protocol summary

Summary

The aim of this this study is evaluation of the effect of Atrovastatin on inflammatory markers in sulfur mutsard gas induced chronic bronchitis. This is a single center, double blind randomized phase III clinical trial. The main inclusion criteria are exposure to mustard gas during the Iran-Iraq war and suffering from chronic bronchitis (history of chronic cough and sputum daily for 3 months during recent 2 years). The main exclusion criteria are using statin in the last 3 months; exacerbation of symptoms in the past 4 weeks; and smoking. We will enroll 90 patients with mustard gas induced chronic bronchitis. Participants will randomly be assigned into intervention and control groups and will receive Atorvastatin (40 mg per day) and placebo (one tablet per day) respectively for 3 months. As the primary outcome of our study, the level of IL 6, TNFa, procalcitonin, and hs-CRPwill be measured before and after intervention. We will compare the results between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904144312N1**
Registration date: **2014-08-16, 1393/05/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-08-16, 1393/05/25

Registrant information

Name

Seyed Masoom Masoompour

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3647 4316

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masoomm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Partly by Shiraz University of Medical Sciences and partly by Project Director will be provided

Expected recruitment start date

2014-06-29, 1393/04/08

Expected recruitment end date

2015-06-29, 1394/04/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Atrovastatin on inflammatory markers in sulfur mutsard gas induced chronic bronchitis

Public title

Effect of Atrovastatin on lung inflammation in bronchitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: exposure to mustard gas during the Iran-Iraq war and have suffered from chronic bronchitis (history of chronic cough and sputum daily for 3 months during recent 2 years) Exclusion criteria: Using statin in the last 3 months of study starting time; exacerbation of symptoms in the past 4 weeks; connective tissue disease; sarcoidosis; eosinophilic granuloma; pneumoconiosis; lymphoma; carcinomatous; smokers

Age

From **45 years** old to **75 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City

Shiraz

Postal code

Approval date

2014-06-28, 1393/04/07

Ethics committee reference number

CT-P-9378-7109

Health conditions studied

1

Description of health condition studied

Chronic bronchitis

ICD-10 code

j44

ICD-10 code description

Chronic bronchitis: obstructive

Primary outcomes

1

Description

TNF alpha level

Timepoint

before intervention - 3 month after intervention

Method of measurement

ELISA test is performed

2

Description

interleukin 6 level

Timepoint

before intervention - 3 month after intervention

Method of measurement

ELISA test is performed

3

Description

Added at 2015-08-05: Procalcitonin

Timepoint

Added at 2015-08-05: At the beginning of the intervention and 3 months after intervention

Method of measurement

Added at 2015-08-05: ELISA

Secondary outcomes

1

Description

Withe blood cell count

Timepoint

before intervention - 3 month after intervention

Method of measurement

Complete Blood Count

2

Description

Added at 2015-08-05: hs-CRP

Timepoint

Added at 2015-08-05: At the beginning the intervention and 3 months after intervention

Method of measurement

Added at 2015-08-05: Immunoassay

Intervention groups

1

Description

Intervention group:40 mg atorvastatin daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: one placebo tablet daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammd Rasul allah Clinic
Full name of responsible person
Dr Seyed Masoom Masoompour
Street address
Pasdarn Blvd, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shiraz University Of medical Science
Full name of responsible person
Dr Seyed Baser Hashemi
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shiraz University Of medical Science
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

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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