

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

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

#### Protocol summary

##### Summary

The aim of this study is evaluation of the effect of Atrovastatin on inflammatory markers in sulfur mustard 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 Atrovastatin (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, TNF $\alpha$ , procalcitonin, and hs-CRP will 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)

##### Phone

+98 71 3647 4316

##### Email address

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 mustard 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**

With 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

**City**

shiraz

## 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

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr seyed Masoom Masoompour

**Position**

Associate professor

**Other areas of specialty/work**

**Street address**

Internal Medicine Department, Nemazee Hospital,  
Nemazee Squ

**City**

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+98 71 1647 4316

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masoomm@sums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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seyed Masoom Masoompour

**Position**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seyed Masoom Masoompour

**Position**

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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*