

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Atorvastatin effect on lung function and serum level of hs-CRP in chemical warfare patients with obstructive pulmonary disease.

Protocol summary

Summary

High sensitive CRP is used as a marker of systemic inflammation in pulmonary disease. Results have shown an anti-inflammatory effect of atorvastatin in cardiopulmonary disease. Thus, this study was undertaken to assess the effect of atorvastatin on serum hs-CRP in chemical warfare victims. We studied 50 patients with mustard lung injury and high serum level of hs-CRP in a double blind, prospective study from Feb., 2011 to Dec., 2011 in Emam Khomeini Hospital, Ardabil, IRAN. Chemical warfare victims with pulmonary disease, who fulfilled entry criteria, were invited to participate in this study. Demographic data (height, weight, body mass index, blood pressure, drug history), COPD assessment test and St. George respiratory questionnaire are completed by patients. Then, pulseoximetry, spirometry and 6 minute walk distance tests are administered. Blood sample is drawn for serum hs-CRP level analysis. Coded pockets (from 1 to 50) containing atorvastatin and placebo (A or B codes) are randomly assigned by a nurse to the patients and the control groups (double blind). 40 mg atorvastatin tablets and the placebo are prescribed once daily for 9 weeks. After 4 weeks of intervention complete examination, pulseoximetry, spirometry and drug side effects are conducted by physician. At the end of the 9th weeks, physical examination, spirometry, pulseoximetry, St. George respiratory questionnaire, 6 minute walk distance test and blood sampling for hs-CRP will be conducted. It should be mentioned that, the patients are informed about the study and in the case of full written consult they are entered in the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101095579N1**

Registration date: **2011-11-13, 1390/08/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-11-13, 1390/08/22

Registrant information

Name

Hassan Ghobadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3325 1401

Email address

h.ghobadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University Of Medical Sciences

Expected recruitment start date

2011-02-04, 1389/11/15

Expected recruitment end date

2011-12-06, 1390/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Atorvastatin effect on lung function and serum level of hs-CRP in chemical warfare patients with obstructive pulmonary disease.

Public title

Aatorvastatin effect on lung function and serum level of hs-CRP in chemical warfare patients with obstructive pulmonary disease.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Chemical warfare victims with obstructive pulmonary disease; age between 35-85; clinically stable disease in previous 8 weeks; acceptance of study design by patients. Exclusion criteria: Active infectious disease; bronchiectasis; chronic inflammatory diseases; soft tissue diseases; active liver and kidney diseases; cancer; cardiac disease (myocardial infarction and unstable angina in previous 6 months); sensitivity to atorvastatin; myopathy; myositis; hypercholesterolemia history; history of atorvastatin consumption; history of smoking; asthma; elevated CPK and elevated liver function test more than twice.

Age

From **35 years** old to **85 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ardabil University Of Medical Sciences

Street address

Ardabil University Of Medical Sciences, Daneshgah street

City

Ardabil

Postal code

56198-53141

Approval date

2011-09-08, 1390/06/17

Ethics committee reference number

6/902

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

(J00-J99)

ICD-10 code description

Chronic lower respiratory diseases

Primary outcomes

1

Description

COPD Assessment Test (CAT) questionnaire

Timepoint

At the beginning of study and 9 weeks after intervention

Method of measurement

CAT questionnaire score (score from 0 to 40)

2

Description

Six Minute Walk Distance Test (6MWDT)

Timepoint

At the beginning of study, 4 weeks and 9 weeks after intervention

Method of measurement

Distance walked in six minute (Meter)

3

Description

Pulmonary volumes

Timepoint

At the beginning of study, 4 weeks and 9 weeks after intervention

Method of measurement

Spirometry

4

Description

The level of hs-CRP

Timepoint

At the beginning of study and 9 weeks after intervention

Method of measurement

Laboratory

5

Description

St. George Respiratory Questionnaire

Timepoint

At the beginning of study and 9 weeks after intervention

Method of measurement

The questionnaire of assessing symptoms score, activity score, impact score and total score

Secondary outcomes

1

Description

O2 saturation of arterial blood

Timepoint

At the beginning of study, 4 weeks and 9 weeks after intervention

Method of measurement

Pulse oximetry device

2

Description

Atorvastatin side effects

Timepoint

4 weeks and 9 weeks after intervention

Method of measurement

According to patient symptoms

Intervention groups

1

Description

In intervention group: Atorvastatin, 40 mg tablet, once daily for 9 weeks

Category

Treatment - Drugs

2

Description

In control group: The placebo tablet, once daily for 9 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pulmonary Clinics Of Emam Khomeini Hospital,
Ardabil

Full name of responsible person

Afsoun Mahmoudpour, Internal medicine resident

Street address

Emam Khomeini Hospital, Shahid Jeddi street, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University Of Medical Sciences

Full name of responsible person

Vice-president for research affair

Street address

Ardabil University Of Medical Sciences, Daneshgah
street

City

Ardabil

Grant name

1290007

Grant code / Reference number

10506

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil 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

Ardabil University Of Medical Sciences

Full name of responsible person

Afsoun Mahmoudpour

Position

Internal medicine resident

Other areas of specialty/work

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Pulmonologist, Internal Medicine Department

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Full name of responsible person

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Position

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

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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