

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of treatment with atorvastatin on serum levels of periostin and interleukin 13 compared with placebo in asthmatic patients

Protocol summary

Summary

(1) Objectives: The aim of this study was to determine the effect of treatment with atorvastatin on serum levels of periostin and interleukin 13 compared with placebo in patients with asthma. (2) Design: Double-blind, randomized, placebo-controlled, phase 3 clinical trial (3) Setting and conduct: Patients are randomly divided into two groups of 40, and after obtaining informed consent, they are included in the study. Researchers are blind to patient and control allocation. (4) Participants: Major inclusion criteria: Patients with chronic asthma symptoms of more than one year duration, aged 18-60 years are enrolled. Major exclusion criteria: lower respiratory tract infection 4 weeks before entering the study; more than 10 pack-year of smoking; pregnancy or breastfeeding; current use of statins or drugs that interact with statins. (5) Interventions: The intervention group treat with atorvastatin 40 mg once daily for 8 weeks, while the control group receive placebo. Asthma controller therapies do not change. (6) Main outcome variables: serum levels of periostin and serum levels of interleukin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102216367N2**

Registration date: **2017-11-15, 1396/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-15, 1396/08/24

Registrant information

Name

Samrad Mehrabi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with atorvastatin on serum levels of periostin and interleukin 13 compared with placebo in asthmatic patients

Public title

Effect of treatment with atorvastatin on asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Asthma patients with a history of more than one year, aged 18 till 60 years are enrolled.

Exclusion criteria: Lower respiratory infection 4 weeks before entering the study; more than 10 pack-year of smoking or smoking in the last 3 months; pregnancy or

breastfeeding; current use of statins or previous side effects of statin or drugs that interact with statins such as antifungal, antibiotic macrolide, cyclosporine, germifibrosil, verapamil and amiodarone; hepatitis or active liver disease; myopathy or myositis.

Age

From **18 years** old to **60 years** old

Gender

Both

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

Postal code

14336 - 71348

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

15216

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45.8

ICD-10 code description

Mixed Asthma

Primary outcomes

1

Description

Serum level of periostin

Timepoint

Before intervention and eight weeks after intervention

Method of measurement

ng/mL

2

Description

Serum level of IL-13

Timepoint

Before intervention and eight weeks after intervention

Method of measurement

pg/mL

Secondary outcomes

1

Description

Adverse drug/placebo reaction

Timepoint

4 and 8 weeks after intervention

Method of measurement

Ask from the patient and laboratory data

2

Description

Forced expiratory volume in first second

Timepoint

Before intervention and 4 and 8 weeks later

Method of measurement

liters per minute

Intervention groups

1

Description

Intervention group: Tablets of Atorvastatin are product of IRAN and 40 mg. Therapy is with one tablet daily for eight weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo will be given 1 times daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Lung clinic

Full name of responsible person

Samrad Mehrabi

Street address

Motahhari clinic, Namazi Sq

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, 7th floor, Central building of SUMS, Zand Ave

Full name of responsible person

Seyed Basir Hashemi

Street address

Vice chancellor for research, 7th floor, Central building of SUMS, 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

Vice chancellor for research, 7th floor, Central building of SUMS, Zand Ave

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

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Full name of responsible person

Samrad Mehrabi

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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