Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of treatment with atorvastatin on serum levels of periostin and interleukin 13 comapred 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 interaction 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
Country
Iran (Islamic Republic of)
Phone
+98 71 3647 4316
Email address
mehrabis@sums.ac.ir

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 comapred 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
Befor intervention and eight weeks after intervention

Method of measurement
ng/mL

2

Description
Serum level of IL-13

Timepoint
Befor 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
Shiraz University of Medical Sciences
Full name of responsible person
Samrad Mehrabi
Position
Assistant professor of medicine
Other areas of specialty/work
Street address
Department of internal medicine, Namazi hospital, Namazi Sq
City
Shiraz
Postal code
Phone
+98 71 3647 4316
Fax
Email
mehrabis@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Samrad Mehrabi
Position
Assistant professor of medicine
Other areas of specialty/work
Street address
Department of Internal Medicine, Namazi hospital, Namazi Sq
City
Shiraz
Postal code
Phone
+98 71 3647 4316
Fax
Email
mehrabis@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Samrad Mehrabi
Position
Assistant professor of medicine
Other areas of specialty/work
Street address
Department of internal medicine, Namazi hospital,Nanazi Sq
City
Shiraz
Postal code
Phone
+98 71 3647 4316
Fax
Email
mehrabis@sums.ac.ir
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