

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effects of atorvastatin on lung function in asthmatic patients under treatment with high dose inhaled steroid or oral steroid

Protocol summary

Summary

Objective: To evaluate the effect of atorvastatin on lung function in asthmatic patients under treatment with high dose inhaled steroid or oral steroid Methods: Sixty seven patients with moderate to severe asthma were entered in an eight-week triple blind randomized controlled trial comparing the effect of oral atorvastatin 40 mg daily with a matched placebo on lung function, airway inflammation and the level of asthma control. Patients spirometric features (FEV1, FVC, FEV1 /FVC, FEF 25-75%), inflammatory biomarkers (ESR, hs-CRP) and asthma control questionnaire scores were measured every 4 weeks during the course. Fifty patients completed the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903114085N1**

Registration date: **2008-02-20, 1386/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-02-20, 1386/12/01

Registrant information

Name

Sayeh Heidari nejad

Name of organization / entity

Guilan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1554 1001

Email address

rrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Guilan university of medical sciences

Expected recruitment start date

2008-02-20, 1386/12/01

Expected recruitment end date

2008-10-06, 1387/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of atorvastatin on lung function in asthmatic patients under treatment with high dose inhaled steroid or oral steroid

Public title

Effects of atorvastatin on asthmatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 18 to 70 years, moderate to severe persistent asthma, under maintenance therapy with high dose inhaled corticosteroid and any dose of oral corticosteroid, under stable medication for the four preceding weeks before randomization, being admitted to respiratory clinic of Razi medical center (Rasht, Guilan province) Exclusion criteria: current smoking or ex-smoking more than 5 pack-year, pregnancy, lactation, any associated diseases, receiving statins or any statin interacting drugs, occurrence of any asthmatic attack during the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

1

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-chancellor for Research, Guilan university of medical sciences

Street address

Vice-chancellor for Research building, Shahid Siadati street, Namjoo avenue,

City

Rasht

Postal code

41446-68164

Approval date

2007-05-21, 1386/02/31

Ethics committee reference number

1680

Health conditions studied**1****Description of health condition studied**

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes**1****Description**

FEV1

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

spirometry

2**Description**

FVC

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

spirometry

3**Description**

FEV1/FVC

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

spirometry

4**Description**

FEF25-75%

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

spirometry

5**Description**

hs-CRP

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

blood sample, micg/ml

6**Description**

ESR

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

blood sample, mm/h

7**Description**

asthma control level

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement
asthma control test (ACT)

Secondary outcomes

1

Description

creatinine kinase(CPK)

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

blood sample, IU/L

2

Description

liver function test

Timepoint

at the beginning of the study and every 1-month interval until 2months

Method of measurement

blood sample,IU/L

3

Description

(Beta hCG) pregnancy test

Timepoint

at the beginning of the study and every 1 month interval until 2 months

Method of measurement

blood sample, mIU/ml

Intervention groups

1

Description

Atrovastatin 40mg tablet, daily, for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo 40mg tablet, daily, for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Seyyed Ali Alavi Foumani

Street address

Sardar Jangal street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research assistant of Guilan University of Medical Science

Full name of responsible person

Dr Abdolrasool Sobhani

Street address

Shahid siadati street, Namjoo avenue

City

Rasht

Grant name

124-610

Grant code / Reference number

10506

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

Yes

Title of funding source

Research assistant of Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Seyyed Ali Alavi Foumani

Position

Assistant professor / MD

Other areas of specialty/work

Street address

Sardar Jangal street, Razi hospital

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 1001

Fax

+98 13 1553 0169

Email

rrc@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Fatemeh Nejatifar

Position

MD

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

Razi hospital, Sardar Jangal street

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 1001

Fax

+98 13 1553 0169

Email

dr_f_nejatifar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Sayeh Heidari Nejad

Position

MD

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

Razi hospital, Sardar Jangal street

City

Rasht

Postal code

41448-95655

Phone

+98 13 1554 1001

Fax

+98 13 1553 0169

Email

sayeh.h1360@gmail.com

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