# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Nov 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)

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+98 13 1554 1001

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**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 begining of the study and every 1 month interval until 2 months
**Method of measurement**
spirometry

### 2

**Description**
FVC
**Timepoint**
at the begining of the study and every 1 month interval until 2 months
**Method of measurement**
spirometry

### 3

**Description**
FEV1/FVC
**Timepoint**
at the begining of the study and every 1 month interval until 2 months
**Method of measurement**
spirometry

### 4

**Description**
FEF25-75%
**Timepoint**
at the begining of the study and every 1 month interval until 2 months
**Method of measurement**
spirometry

### 5

**Description**
hs-CRP
**Timepoint**
at the begining of the study and every 1 month interval until 2 months
**Method of measurement**
blood sample,micg/ml

### 6

**Description**
ESR
**Timepoint**
at the begining 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 begining 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 begining 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 begining 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 begining 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*