Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Atrvastatyn effect in treating patients with asthma

Protocol summary

Summary

This study is a randomized double blind clinical trials will be conducted on 62 asthmatic patients (intervention and control group, each 31 cases) the inclusion criteria included patients with mild persistent to moderate persistent asthma (grade 2 and 3 criteria, the severity of asthma) and exclusion criteria included pregnancy, people which currently taking statin drugs, history of sensitivity to statin drugs, history of hospitalization during the last month, smokers, history of hepatitis or active liver disease, myopathy or myositis. intervention Group treated with atorvastatin tablets 40 mg oral daily dose for 8 weeks and control group during this period will receive placebo. At the onset of the study after obtaining informed consent, the standard questionnaire of asthma control test (ACT) will be filled out by patients followed by a spirometry. A blood sample to measure the number of peripheral blood eosinophil, serum low-density lipoprotein, high density lipoprotein, total cholesterol and triglycerides are taken from the patient. Four weeks after the treatment of asthma, control questionnaire will be complete again and re-matched patients with possible side effects of the drugs and asthma control level. Finally, after eight weeks of treatment, again filling the questionnaire asthma control and Spirometry is taken from patients. blood samples to determine changes in the number peripheral blood eosinophil, serum total cholesterol and triglyceride is taken. The expected primary outcome was improve the degree of control of clinical asthma symptoms based on the asthma controlled test (ACT) Expected secondary outcomes include to improve pulmonary volumes [percent of forced expiratory volume in one second (% 1FEV) and percentage of vital capacity (% FVC)] and decrease the number of peripheral blood eosinophil. Maintenance treatment of asthmatic patients are not altered. At the begining and the end of the study to assess drug compliance of the patients, Serum cholesterol and TG measurement tests will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104236257N1**
Registration date: **2011-05-25, 1390/03/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-05-25, 1390/03/04

Registrant information

Name
Abdollatif Moini
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 1221 5812
Email address
dr.moini@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2010-10-24, 1389/08/02

Expected recruitment end date

2011-04-10, 1390/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Atrvastatyn effect in treating patients with asthma

Public title
Effect of statins in treating patients with asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria included: patients with mild persistent to moderate persistent asthma (grade 2 and 3 criteria, the severity of asthma), age 18 to 70 years and acceptance of written consent. Exclusion criteria included: pregnancy, people who currently are taking statin drugs , history of sensitivity to statin drugs, History of hospitalization during a month before the research, smokers, history of hepatitis or active liver disease ,myopathy or myositis
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **31**
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
Medical Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences
City
Arak
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
3-40-87

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45.9
ICD-10 code description
Asthma, unspecified

Primary outcomes

1

Description
The expected primary outcome was improvement in the degree of clinical control of asthma symptoms [base on standardized Asthma Control Test (ACT)]
Timepoint
At the onset of the study and 8 week after treatment with atorvastatin
Method of measurement
base on standardized Asthma Control Test (ACT)

Secondary outcomes

1

Description
Secondary outcomes included lung volumes [percent of forced expiratory volume in one second (FEV1 %) and percent of forced vital capacity (FVC%)] and reduction of the number of peripheral blood eosinophils
Timepoint
At the onset of the study and 8 week after treatment with atorvastatin
Method of measurement
spirometry and peripheral blood sample

Intervention groups

1

Description
31 patients were selected as intervention group and treat with atorvastatin tablets (by: Sobhan Pharmaceutical Company) 40 milligram daily for 8 weeks . At the begining of the study after obtaining formal consent, the standard questionnaire of asthma control test (ACT) is filled out and followed by a spirometry; also a peripheral blood sample is taken to measure blood eosinophil counts and patients' serum low density lipoprotein-cholesterol(LDL-C), low density lipoprotein-cholesterol (HDL-C), total cholesterol, and TG levels. Serum cholesterol and TG measurement tests is applyied to evaluate the adherence of the patients. For spiromety, Desktop spirometer device, Pony FX model, made in Italy is used. Four weeks after treatment,asthma control test (ACT) questionnaire will be re-administered and the patients visit for possible side effects of drugs and

asthma control level. Finally, after 8 weeks of treatment, the patiants took the asthma control test (ACT) questionnaire, and a spirometry is taken from patients. Also, another peripheral blood sample is taken to determine changes in the peripheral blood eosinophil count and serum cholesterol and TG levels.

Category

Treatment - Drugs

2

Description

31 patients were selected as Control group and receive placebo daily for 8 weeks . At the begining of the study after obtaining formal consent, the standard questionnaire of asthma control test (ACT) is filled out and followed by a spirometry; also a peripheral blood sample is taken to measure blood eosinophil counts and patients' serum low density lipoprotein-cholesterol(LDL-C), low density lipoprotein-cholesterol (HDL-C), total cholesterol, and TG levels. For spiromety, Desktop spirometer device, Pony FX model, made in Italy is used. Four weeks after treatment,asthma control test (ACT) questionnaire will be re-administered and the patients visit for asthma control level. Finally, after 8 weeks of treatment, the patiants took the asthma control test (ACT) questionnaire, and a spirometry is taken from patients. Also, another peripheral blood sample is taken to determine changes in the peripheral blood eosinophil count and serum cholesterol and TG levels

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-almomenin Hospital

Full name of responsible person

Abdollatif Moini

Street address

Arak, Amir-almomenin Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Said Changhizi Ashtiani

Street address

Arak University of Medical Sciences, Deputy of Education & Research

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Abdollatif Moini

Position

pulmonologist, Assistant Professor

Other areas of specialty/work

Street address

Iran Internal Medicin Department of Amir-al-momenin Haspital

City

Arak

Postal code

Phone

+98 86 1222 5202

Fax

Email

dr.moini@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Abdollatif Moini

Position

pulmonologist, Assistant Professor

Other areas of specialty/work

Street address

internal Medicine Department of Amir-al-momenin Haspital- Arak- Iran

City

Arak

Postal code

Phone

+98 86 1222 5202

Fax

+98 86 1417 3630

Email
dr.moini@arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Abdollatif Moini
Position
pulmonologist, Assistant Professor
Other areas of specialty/work
Street address
internal Medicine Department of Amir-al-momenin Haspital- Sardasht- Arak
City
Arak
Postal code
Phone
+98 86 1222 5202
Fax
Email
dr.moini@arakmu.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