

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

Abdollahif Moini

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

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 beginning 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 applied to evaluate the adherence of the patients. For spirometry, 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 patients 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 patients 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

Abdollahatif Moini

Street address

Arak, Amir-almomenin Hospital

City

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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

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Position

pulmonologist, Assistant Professor

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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