

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of atorvastatin effects with placebo on pulmonary pressure in COPD patients

Protocol summary

Summary

The aim of this double blind controlled clinical trial is to evaluate of Atorvastatin effect on Pulmonary Arterial pressure (PAP) in patients with chronic obstructive pulmonary disease (COPD). In this study 70 patients with COPD (based on spirometric criteria) and PAP>25mm Hg will randomly (odd numbers for intervention group and even numbers for control) divided into two groups (n=35); intervention (cap atorvastatin, 40mg/day for 3 months) and control (cap placebo, 1 cap/day for 3 months). Patients and responsible physicians will be blind. Demographic data, the results of right ventricle (RV) echocardiographic study (RV size and ejection fraction) and the results of 6 minute walk test (systolic and diastolic blood pressure and o2 saturation before and after of the test and total distance) prior to intervention and 3 months later will compared between two groups. The history of allergy to atorvastatin, cardiac diseases, stroke in recent 3 months and COPD exacerbation are exclusion criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051213299N1**

Registration date: **2013-06-27, 1392/04/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-27, 1392/04/06

Registrant information

Name

Ali Cheraghi

Name of organization / entity

Arak University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 86 1222 2004

Email address

dralicheraghi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Arak University of Medical Sciences.

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of atorvastatin effects with placebo on pulmonary pressure in COPD patients

Public title

Atorvastatin and Pulmonary Pressure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Resting pulmonary blood pressure>25mmHg; functional class II, III; ability of take part in 6 min walk test. Exclusion criteria: Cardiac diseases, Systolic blood pressure>180mmHg, Diastolic blood pressure>100mmHg, Heart rate>120/min; heart failure (LVEF<50%); no compliance, history of allergy to atorvastatin, COPD exacerbation; stroke in recent 3 months.

Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
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
Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Sardasht Sq.,
Arak.
City
Arak
Postal code
Approval date
2012-05-30, 1391/03/10
Ethics committee reference number
91-127-5

Health conditions studied

1
Description of health condition studied
COPD
ICD-10 code
J44
ICD-10 code description
Chronic lower respiratory diseases

2
Description of health condition studied
Pulmonary hypertension
ICD-10 code
I27.9
ICD-10 code description

Pulmonary heart disease, unspecified

Primary outcomes

1
Description
Pulmonary Artery Blood Pressure
Timepoint
before and 3 months after intervention
Method of measurement
Echocardiographic study

2
Description
Right ventricle ejection fraction
Timepoint
Before intervention and 3 months later
Method of measurement
TAPSE in Echocardiographic study

3
Description
Systolic Blood Pressure
Timepoint
Before and after 6 minute walk test, before and 3 months
after intervention
Method of measurement
mmHg, Mercury barometer

4
Description
Diastolic Blood Pressure
Timepoint
before and after of 6 minute walk test, before and 3
months after intervention
Method of measurement
mmHg, Mercury barometer

5
Description
Heart Rate
Timepoint
before and after 6 minute walk test, before and 3 months
after intervention
Method of measurement
Rate/ Minute

6
Description
Total distance in 6MWT
Timepoint
before and 3 months after intervention
Method of measurement
Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cap Atorvastatin, 40 mg/day, for 3 months

Category

Treatment - Drugs

2

Description

Control group: Atorvastatin like placebo cap , 1cap/day for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Almomenin Hospital

Full name of responsible person

Ali Cheraghi

Street address

Internal ward, Amir Almomenin Hospital, Sardasht sq., Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Arak University of Medical Sciences

Full name of responsible person

Saeed Changizi Ashtyani

Street address

Arak, Sardasht sq., Arak University of Medical Sciences

City

Arak

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 of 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

Ali Cheraghi

Position

Resident of Internal Medicine

Other areas of specialty/work

Street address

Amir Almomenin Hospital, Arak University of Medical Sciences, Sardasht Sq., Arak

City

Arak

Postal code

Phone

+98 86 1417 3517

Fax

Email

dralicheraghi@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

Latif Moeini

Position

Sub Specialist of Lung Diseases

Other areas of specialty/work

Street address

Vali Asr Hospital, Vali Asr Sq., Arak University of Medical Sciences

City

Arak

Postal code

Phone

+98 86 1222 2004

Fax

Email

dralicheraghi@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

Ali Cheraghi

Position

Resident of Internal Medicine

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

Amir Almomenin Hospital, Sardasht Sq., Arak

City

Arak

Postal code**Phone**

00

Fax**Email****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