

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 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

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#### 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

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+98 86 1222 2004

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#### 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**

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**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*