

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of atorvastatin on the treatment of secondary pulmonary hypertension due to chronic obstructive air way diseases

Protocol summary

Summary

Aim: The assessment of therapeutic effects of atorvastatin in patients with pulmonary arterial hypertension (PAH) due to chronic obstructive pulmonary disease (COPD). This study is a triple randomized controlled trial, unicenter that patients with secondary pulmonary hypertension due to COPD who are referred to Rasoul Akram hospital and they have 18-80 years old, systolic pulmonary arterial hypertension (SPAP)>40mmhg, LDL>70mg/dl, ALT and AST<3 times upper limit normal, no drug history of prostanoids, statins, endothelin antagonists and phosphodiesterases, able to doing 6-min walk test and obstructive pattern in spirometry are selected and randomized in two groups. Our pretreatment evaluations include CRP, Spirometry, Echocardiography, patients` signs and symptoms, and then they are randomized to receive either atorvastatin 40 mg/d or placebo in addition to current treatment for 6 months. The primary outcome is SPAP at 6 months after randomization and secondary outcomes include cardiac output (CO), right ventricular size, CRP, 6 min walk distance test, spirometry parameters and changes in signs and symptoms. Finally, primary and secondary outcomes will be evaluated after six months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108257411N1**
Registration date: **2012-05-20, 1391/02/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-20, 1391/02/31

Registrant information

Name

Hanieh Raji

Name of organization / entity

Imam Khomeini hospital

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6501

Email address

raji-h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2009-03-20, 1387/12/30

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of atorvastatin on the treatment of secondary pulmonary hypertension due to chronic obstructive air way diseases

Public title

The effect of atorvastatin on the treatment of secondary pulmonary hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Systolic pulmonary hypertension>40mmhg; age 18 years or over until 80; no drug history of prostanoids, statins, endothelin

antagonists and phosphodiesterase; able to doing 6-min walk test; obstructive pattern in PFT and functional class 2,3 (NYHA). Exclusion criteria: PAH from a cause other COPD; LDL<70 mg/dl; ALT or AST> 3x ULN.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Tehran university of medical sciences

Street address

Hemmat high way, Pardis e Hemmat,Tehran
university of medical sciences

City

Tehran

Postal code**Approval date**

2009-05-14, 1388/02/24

Ethics committee reference number

310/90-116

Health conditions studied**1****Description of health condition studied**

secondary pulmonary hypertension

ICD-10 code

J40-J47

ICD-10 code description

Chronic lower respiratory diseases

Primary outcomes**1****Description**

Systolic pulmonary hypertension

Timepoint

At the beginning of study and 6 months later

Method of measurement

Echocardiography

Secondary outcomes**1****Description**

CRP

Timepoint

At the beginning of study and 6 months later

Method of measurement

Lab data

2**Description**

Cardiac output

Timepoint

At the beginning of study and 6 months later

Method of measurement

Echocardiography

3**Description**

Right ventricular size

Timepoint

At the beginning of study and 6 months later

Method of measurement

Echocardiography

4**Description**

6 min walk test

Timepoint

At the beginning of study and 6 months later

Method of measurement

By researcher

5**Description**

FEV1, FVC, FEV1/FVC

Timepoint

At the beginning of study and 6 months later

Method of measurement

Spirometry

6**Description**

Adverse effect of drug

Timepoint

One month after beginning and the end of treatment

Method of measurement

By lab data and symptoms

Intervention groups

1

Description

Tab atorvastatin 20 mg BID (twice a day) in case group

Category

Treatment - Drugs

2

Description

placebo in control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Tehran university of medical sciences, Hemmat Pardis

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran university of medical sciences

Full name of responsible person

Dr. Seied Alijavad Moosavi

Position

Pulmonologist

Other areas of specialty/work

Street address

Rasoul Akram Hospital, Niaiesh street, Sattarkhan

City

Tehran

Postal code

Phone

+98 21 4465 9771

Fax

Email

Dr_moosavi_pul@yahoo.ca

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Dr. Seied Alijavad Moosavi

Position

Pulmonologist

Other areas of specialty/work

Street address

Rasoul Akram Hospital, Niaiesh Street, Sattarkhan

City

Tehran

Postal code

Phone

+98 21 4465 9771

Fax

Email

dr_moosavi_pul@yahoo.ca

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Dr. Hanieh Raji

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

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