

# 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

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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*