# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Investigation of The effects of statins on pulmonary artery pressure in the patients with chronic obstructive pulmonary disease

## Protocol summary

**Summary**

Chronic obstructive pulmonary disease is the fourth leading cause of death in the world and more than ten million people caught the disease in America. Due to the importance of chronic obstructive pulmonary disease in public health around the world, we aimed to investigate The effects of statins on pulmonary artery pressure in the patients with chronic obstructive pulmonary disease. This triple blind, randomized control trials will perform on 21 COPD patients with atorvastatin treatment and 21 COPD patients without receiving any treatment who attended to Vali-Asr hospital, Birjand, East of Iran 2016. Inclusion criteria were as follow: no previous use of statins, Performing CBC, lipid profile, LTF, absence of liver disease, FEV1<80% and FEV1/FVC<70%. Also, patients excluded for the following reasons: discontinuation of statin therapy during the study, having advanced heart disease, the advent of statin therapy complications, long-term use of corticosteroid and death. Both groups will tested with echocardiography for presence of pulmonary hypertension by a cardiologist before taking atorvastatin and their pulmonary artery pressure will measured at baseline. In addition, Spirometry will perform in both groups. Case group receive 40mg statins per day for six month (24 weeks). At the end of this study, patients evaluate by spirometry and echocardiography.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016042527594N1**
Registration date: **2016-06-26, 1395/04/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-06-26, 1395/04/06

**Registrant information**

**Name**

Morteza Hajihosseini

**Name of organization / entity**

Birjand University of Medical sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 937 625 0645

**Email address**

m.hajihosseini@bums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Birjand University of Medical Sciences

**Expected recruitment start date**

2016-05-15, 1395/02/26

**Expected recruitment end date**

2016-11-15, 1395/08/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of The effects of statins on pulmonary artery pressure in the patients with chronic obstructive pulmonary disease

**Public title**

Effects of statins on pulmonary artery pressure in the patients with chronic obstructive pulmonary disease

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: no previous use of statins; Performing CBC; lipid profile; LTF; absence of liver disease; FEV1<80%; FEV1/FVC<70%. Exclusion criteria: discontinuation of statin therapy during the study; having advanced heart disease; the advent of statin therapy complications; long-term use of corticosteroid; death

**Age**
From **40 years** old to **80 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **42**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Birjand University of Medical sciences

**Street address**
Birjand University of Medical sciences, Ayatollah Ghafari ST, Birjand

**City**
Birjand

**Postal code**

**Approval date**
2015-01-26, 1393/11/06

**Ethics committee reference number**
03111393

## Health conditions studied

**1**

**Description of health condition studied**
Chronic Obstructive Pulmonary Disease

**ICD-10 code**
J44

**ICD-10 code description**
Chronic obstructive pulmonary disease

## Primary outcomes

**1**

**Description**
Pulmonary Artery Pressure changes

**Timepoint**
Befor and After drug use

**Method of measurement**
Echocadiography

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Receiving statin 40 miligram per day for six month

**Category**
Treatment - Drugs

**2**

**Description**
Control group: Receiving nothing

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Valiasr Hospital

**Full name of responsible person**
Anahita Aryan

**Street address**
Valiasr Hospital, Ayatollah Ghafari ST, Birjand

**City**
Birjand

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice chancellor for research, Birjand University of Medical sciences

**Full name of responsible person**
Gholamreza Sharifzade

**Street address**
Birjand University of Medical sciences, Ayatollah Ghafari ST, Birjand

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Birjand

**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, Birjand 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**
Birjand University of Medical sciences
**Full name of responsible person**
Anahita Aryan
**Position**
Resident of Internal Medicine
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## Person responsible for scientific inquiries

**Contact**
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Valiasr Hospital
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MD
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## Person responsible for updating data

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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*