

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effects of pentoxifylline on 6-minute walk test parameters in patients with pulmonary hypertension due to chronic obstructive pulmonary diseases

#### Protocol summary

##### Summary

Objective: To determine the effects of pentoxifylline (Ptx) on exercise tolerance and hypoxemia in patients with severe and very severe chronic obstructive pulmonary diseases (COPD). Design: Randomized double-blind clinical trial Setting and conduct: Department of Pulmonary Medicine, Shahid Faghihi Hospital, Shiraz University of Medical Sciences. Six-minute walk test, dyspnea score, and oxygen saturation by pulse oximeter were performed in eligible patients. They were then randomized to receive Ptx (400 mg TID) or placebo for 12 weeks. Participants: Twenty eight patients with severe and very severe COPD and pulmonary hypertension. The inclusion criteria: Severe to very severe COPD according to the Global Initiative for Chronic Obstructive Lung Diseases (GOLD) criteria [forced expiratory volume in one sec (FEV1)/forced vital capacity (FVC) < .7], FEV1 of less than 50% of the relevant predicted values, and systolic pulmonary artery pressure (SPAP) greater than 40 mmHg by Color Doppler Echocardiography. Exclusion criteria: History of myocardial infarction or unstable angina pectoris in the previous month, congestive left heart failure, inability to walk due to musculoskeletal disorders for 6 minutes, symptomatic peripheral vascular disorders, systolic blood pressure more than 180 mmHg, diastolic blood pressure more than 120 mmHg before 6-minute-walk test, significant resting or exertional cardiac dysrhythmias Intervention: Pentoxifyllin (400 mg TID) or placebo for 12 weeks. Main outcome measures: Six-minute walk distance, dyspnea score, and oxygen saturation by pulse oximeter

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202018889N1**

Registration date: **2012-09-17, 1391/06/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-09-17, 1391/06/27

##### Registrant information

###### Name

Seiyed Mohammad Ali Ghayumi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1646 7383

###### Email address

ghayyoumim@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2010-11-30, 1389/09/09

##### Expected recruitment end date

2011-02-28, 1389/12/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of pentoxifylline on 6-minute walk test

parameters in patients with pulmonary hypertension due to chronic obstructive pulmonary diseases

#### Public title

The effects of pentoxifylline in severe chronic obstructive pulmonary diseases

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Severe to very severe chronic obstructive pulmonary diseases (COPD) according to the Global initiative for chronic Obstructive Lung Disease (GOLD) criteria [forced expiratory volume in one sec (FEV1)/forced vital capacity (FVC)<.7], FEV1 of less than 50% of the relevant predicted value, and systolic pulmonary artery pressure (SPAP) greater than 40 mmHg measure by Color Doppler Echocardiography. Exclusion criteria: History of myocardial infarction or unstable angina pectoris in the previous month, congestive left heart failure, inability to walk due to musculoskeletal disorders for 6 minutes, symptomatic peripheral vascular disorders, systolic blood pressure more than 180 mmHg, diastolic blood pressure more than 120 mmHg before 6-minute-walk test, significant resting or exertional cardiac dysrhythmias.

#### Age

From **20 years** old to **80 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **28**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

The patients were randomized with simple method using a sequence of random numbers from a textbook of Statistics. Each patient was given a drug package blindly. The data collected from each patient were recorded using a questionnaire labeled with the same of the drug package he/she had received. Two trained nurses performed 6-minutes walk test, pulse oximetry and other measurements. The physician, the nurses, and patients were blind of the content of the drug package

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee , Shiraz University of Medical Sciences

##### Street address

Central Building of Shiraz University of Medical Sciences, Zand Ave

##### City

Shiraz

##### Postal code

##### Approval date

2010-07-10, 1389/04/19

##### Ethics committee reference number

CT -90-5663

## Health conditions studied

### 1

#### Description of health condition studied

Pulmonary Hypertension due to COPD

#### ICD-10 code

I27.2, J 4

#### ICD-10 code description

Chronic Obstructive Pulmonary Disease, Unspecified,Other Secondary Pulmonary Hypertension

## Primary outcomes

### 1

#### Description

Arterial Oxygen Saturation

#### Timepoint

Baseline , 6th week and 12th week after intervention

#### Method of measurement

Pulse Oximetry

### 2

#### Description

6-minute walk distance

#### Timepoint

baseline , 6th and 12th weeks of intervention

#### Method of measurement

6-minute walk test by walking for 6 minutes

### 3

#### Description

dyspnea severity index

#### Timepoint

baseline , 6th week and 12th week after intervention

#### Method of measurement

Borg scale questioner

## Secondary outcomes

1

### Description

Heart Rate

### Timepoint

Baseline , 6th week and 12th week after intervention

### Method of measurement

Pulse Oximetry

## Intervention groups

1

### Description

Pentoxifylline 400 mg tablets (Amin Pharmaceutical Company).

### Category

Treatment - Drugs

2

### Description

Placebo with identical appearance to that of pentoxifylline and composed of methyl cellulose (Department of Pharmaceutics, Shiraz School of Pharmacy, Shiraz University of Medical Sciences).

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Faghihi OPD Clinic

#### Full name of responsible person

Seiyed Mohammad Ali Ghayumi

#### Street address

Internal Medicine OPD Clinic, Shahid Faghihi Hospital, Zand Ave

#### City

Shiraz

2

### Recruitment center

#### Name of recruitment center

Shahid Motahari OPD Clinic

#### Full name of responsible person

Seiyed Mohammad Ali Ghayumi

#### Street address

Internal Medicine, Shahid Motahari OPD Clinic, Zand Ave

#### City

Shiraz

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

#### Full name of responsible person

Dr Gholamreza Hatam

#### Street address

Central Building of Shiraz University of Medical Sciences, Zand Ave

#### City

Shiraz

### 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 Shiraz 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

Department of Internal Medicine , shiraz medical school

#### Full name of responsible person

Seiyed Mohammad Ali Ghayumi

#### Position

Associate Prof. of Pulmonary medicine

#### Other areas of specialty/work

#### Street address

Pulmonary lab, Faghihi hospital, Zand Ave

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ghayyoumim@sums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Department of Internal Medicine, shiraz medical

school

**Full name of responsible person**

Seiyed Mohammad Ali Ghayumi

**Position**

Pulmonary specialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Seiyed Mohammad Ali Ghayumi

**Position**

Associate Prof. of pulmonary medicine

**Other areas of specialty/work**

**Street address**

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**Fax**

**Email**

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**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*