

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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+98 71 1646 7383

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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 Pharmacuetical 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

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2

Recruitment center

Name of recruitment center

Shahid Motahari OPD Clinic

Full name of responsible person

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Internal Medicine, Shahid Motahari OPD Clinic, Zand Ave

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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

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Central Building of Shiraz University of Medical Sciences, Zand Ave

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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

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Position

Associate Prof. of Pulmonary medicine

Other areas of specialty/work

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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