Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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: Pentoxyfillin (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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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 pentoxyfylline 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
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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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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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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
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Person responsible for scientific inquiries

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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