Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Pilot Study of Efficacy and Safety of Cyproheptadine in Pulmonary Arterial Hypertension Patients in Massih Daneshvari Hospital

Protocol summary

Study aim
Evaluation of efficacy and safety of cyproheptadine in patients with pulmonary artery hypertension

Design
This is a 12 weeks pilot study, double-blind, placebo-controlled, parallel-group, phase II, randomized trial with 12 patients

Settings and conduct
patients who have inclusion criteria will receive cyproheptadine 4 mg/daily for 3 months. patients will evaluate before and after the intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with mean pulmonary arterial pressure ≥25 mmHg (confirmed by catheterization at diagnosis time) and symptomatic pulmonary arterial hypertension diagnosis, functional class II or III according to the world health organization classification, ages between 18 and 75 years old, 6-minute walk test distance of 50 to 450 m, patients receiving stable treatments for PAH (the phosphodiesterase-5 inhibitors or the endothelin-receptor antagonist (bosentan) or both at a dose) and having a stable clinical and hemodynamical status for at least 3 months, and use of anticoagulants, calcium channel blocker, and diuretics will be allowed when the medicine or dosage has been unchanged for at least the last 3 months. Exclusion criteria: patients taking narcotics, sedatives, alcohol, hypnotics, monoamine inhibitors (MAOIs), and selective serotonin reuptake inhibitors, angle-closure glaucoma, symptomatic benign prostate hyperplasia, pregnancy and lactation, chronic kidney disease, occupations in which sleepiness is associated with hazards, and BMI≥30 kg/m2.

Intervention groups
interventional groups include intervention group (cyproheptadine) and control group (placebo)

Main outcome variables
6-MW distance, mean-PAP, NT-ProBNP, and FC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130921014727N7**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **retrospective**

Last update: **2021-09-23, 1400/07/01**
Update count: **0**

Registration date
2021-09-23, 1400/07/01

Registrant information

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Shahid Behesti University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Shahid Beheshti University of Medical Sciences, research deputy

Expected recruitment start date
2015-01-20, 1393/10/30

Expected recruitment end date
2015-11-21, 1394/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Pilot Study of Efficacy and Safety of Cyproheptadine in Pulmonary Arterial Hypertension Patients in Massih Daneshvari Hospital

Public title
The Evaluation of Safety and Efficacy of Cyproheptadine in Pulmonary Arterial Hypertension

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with mean pulmonary arterial pressure (mPAP) ≥25 mmHg (confirmed by catheterization at diagnosis time) and symptomatic pulmonary arterial hypertension (PAH) diagnosis functional class (FC) II or III according to the world health organization classification ages between 18 and 75 years old 6-minute walk test (6-MWT) distance of 50 to 450 m patients receiving stable treatments for PAH, the phosphodiesterase-5 inhibitors or the endothelin-receptor antagonist (bosentan) or both at a dose, and were being stable clinical and hemodynamical status for at least 3 months before randomization use of anticoagulants, calcium channel blocker and diuretics will be allowed when the medicine or dosage was unchanged for at least last 3 months
Exclusion criteria:
SSRIs, CCBs, MAOIs, sedatives, hypnotics, and alcohol consumers patients who sleepiness and drowsiness are associated with hazards in their jobs pregnancy and lactation symptomatic prostate hypertrophy BMI≥30 CKD (SCr.2.5, proteinuria>500mg/d) COPD angle-closure glaucoma

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **12**

Randomization (investigator's opinion)
Randomized

Randomization description
in this study we will use unrestricted or simple randomization. the study utilizes individual sampling. we are using a random number table to randomize patients. patients in our center are numbered and even numbers are allocated to the drug group and odd numbers are allocated to the placebo group. numbers on the table select from the top left corner and the direction is toward the bottom right corner. every patient will receive a can containing pills. each pill can is labeled with a specific number that indicates drug or placebo. the numbers' information will have been hidden from patients and researchers by the time of analysis.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each drug label has a number which indicates that the patient using the drug or the placebo. list of numbers are keeping hidden from patients and research team.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of pharmacy, Shahid Behesti University of Medical Sciences

Street address
Niayesh-Valiasr crossing, Faculty of pharmacy

City
tehran

Province
Tehran

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1991953381

Approval date
2014-11-18, 1393/08/27

Ethics committee reference number
2818/پ/ژ

Health conditions studied

1

Description of health condition studied
primary pulmonary hypertension

ICD-10 code
I27.0

ICD-10 code description
Primary pulmonary hypertension

Primary outcomes

1

Description
WHO functional class

Timepoint
At the beginning and 3 months after intervention

Method of measurement
WHO protocol to determine FC

2

Description
6-Minute walk test
Timepoint
At the beginning and 3 months after intervention
Method of measurement
the distance which is walked via test by patient

3

Description
mean PAP
Timepoint
At the beginning and 3 months after intervention
Method of measurement
measuring by transthoracic echocardiography

4

Description
blood level of NT-proBNP
Timepoint
At the beginning and 3 months after intervention
Method of measurement
by blood sample

Secondary outcomes

empty

Intervention groups

1

Description
for intervention group: cyproheptadine 4mg PO q12hr for 3 monthes
Category
Treatment - Drugs

2

Description
for control group: identical placebo tablet q12hr PO for 3 monthes
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Shahab Moradi Haghighat
Street address
Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar Roundabout, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Faculty of Pharmacy, Shahid Behesti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Pharmacy, Shahid Behesti University of Medical Sciences
Full name of responsible person
Shahab Moradi Haghighat
Position
Pharmacist
Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available