# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 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**

**Name**
Fanak Fahimi

**Name of organization / entity**
Shahid Behesti University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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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

**Postal code**
1991953381

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

**Ethics committee reference number**
2818/ژ/پ

## 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**
Faculty of Pharmacy, Shahid Behesti University of Medical Sciences
**Full name of responsible person**
Nima Naderi
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school.pharmacy@sbmu.ac.ir
**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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## Person responsible for scientific inquiries

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Ph.D in Clinical Pharmacy

**Latest degree**

Specialist

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## Person responsible for updating data

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**Name of organization / entity**

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Pharmacist

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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