

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A clinical trial to compare the effectiveness of spironolactone with the standard treatment in right ventricular function in group 1 pulmonary hypertension patients

Protocol summary

Summary

Objective: To compare the effectiveness of spironolactone and normal treatment in right ventricular function in group 1 pulmonary hypertension patients.

Design: A randomized, double-blind, clinical trial based on random number table. **Study population:** Based on the European International Guideline, patients with group 1 pulmonary hypertension who have undergone the routine pulmonary hypertension treatment for at least three months. **Inclusion criteria:** Patients with group 1 pulmonary hypertension; aged between 12 and 76 years. **Exclusion criteria:** Eisenmenger's syndrome; congenital diseases; scleroderma, thalassemia, systemic disease, cirrhosis, cor pulmonale, renal failure; frequent readmission and receiving inotropic therapy; left systolic dysfunction; mental disabilities; pulmonary disease of asthma; and unwillingness to follow up. **Sample size:** 50 cases. **Study intervention:** The control group will receive 10-20 mg of tadalafil and 125 mg of bosentan once or twice a day for four months. The intervention group will receive 25 mg of spironolactone in addition to the standard treatment on a daily basis for four months. **Study outcome:** Evaluation and comparison of the control and intervention groups in terms of systolic and diastolic function of the right ventricle with echo, clinical signs (blood pressure, heart rate, and oxygen saturation) by 6-min walk distance test, and serum NT-ProBNP levels with ELISA before and four months after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT20171120037376N1**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name

Eghane Mobaser

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 4499

Email address

vakilianf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of spironolactone with the standard treatment in right ventricular function in group 1 pulmonary hypertension patients

Public title

The effectiveness of spironolactone in group 1 pulmonary hypertension patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with group 1 pulmonary hypertension; aged between 12 and 76 years. Exclusion criteria: Eisenmenger's syndrome; congenital diseases; scleroderma, thalassemia, systemic disease, cirrhosis, cor pulmonale, renal failure; frequent readmission and receiving inotropic therapy; left systolic dysfunction; mental disabilities; pulmonary disease of asthma; and unwillingness to follow up.

Age

From **12 years** old to **76 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2016-10-07, 1395/07/16

Ethics committee reference number

IR.MUMS.fm.REC.1395.173

Health conditions studied

1

Description of health condition studied

Group 1 pulmonary hypertension

ICD-10 code

I27.8

ICD-10 code description

Other specified pulmonary heart diseases

Primary outcomes

1

Description

Systolic and diastolic function of the right ventricle

Timepoint

Before and four months after treatment

Method of measurement

Echo

2

Description

Clinical signs (blood pressure, heart rate, and oxygen saturation)

Timepoint

Before and four months after treatment

Method of measurement

6MWD test

Secondary outcomes

1

Description

Serum NT-ProBNP levels

Timepoint

Before and four months after treatment

Method of measurement

ELISA

Intervention groups

1

Description

Control group: Who will receive 10-20 mg of tadalafil and 125 mg of bosentan once or twice a day for four months.

Category

Treatment - Drugs

2

Description

Intervention group: Who will receive 10-20 mg of tadalafil and 125 mg of bosentan once or twice a day in addition to 25 mg of spironolactone in addition to the standard treatment on a daily basis for four months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Eghane Mobaser

Street address

Emam Reza Hospital, Doctoral Intersection

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

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, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Eghane Mobaser

Position

Cardiologist

Other areas of specialty/work

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Position

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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