Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity
Mashhad University of Medical Sciences
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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
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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
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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, 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
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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