Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Double blind randomized clinical trial of the Farantan (Bosentan) 125 mg on pulmonary arterial hypertension cases; a product of Faran pharmaceutical Company

Protocol summary

Summary

Aim: The evaluation study of Farantan (Iranian made Bosentan) in treatment of pulmonary arterial hypertension Study: Double blind randomized clinical trial with placebo in control group Inclusion criteria:Secondary cases of pulmonary arterial hypertension in functional class of II or higher Exclusion criteria: intolerance or any severe or relatively severe side effects Study population: Referring cases of pulmonary arterial hypertension to its clinic Sample size:two group, each one 15 participants Intervention: Prescribing Farantan (Iranian made Bosentan), 125 mg twice a day for 2 years Main outcome: 6 minutes walking test Secondary outcomes: clinical evaluations, ProBNP, blood and liver tests

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041417261N1**
Registration date: **2014-04-29, 1393/02/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-04-29, 1393/02/09

Registrant information

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Kayvan Saeedfar
Name of organization / entity
National Research Institute of Tuberculosis and Lung Diseseas
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Faran pharmaceutical company

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind randomized clinical trial of the Farantan (Bosentan) 125 mg on pulmonary arterial hypertension cases; a product of Faran pharmaceutical Company

Public title

The efficacy study of Farantan on pulmonary arterial hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: • The cases of pulmonary arterial hypertension (PAH), secondary to cardiac or connective tissue disorders (e.g. scleroderma, Eisenmenger's syndrome, etc.), which are in functional class II or higher (Due to drug deficiency and national guideline, Traclleer has not been prescribed for these patients, so far); • No finding of anemia, liver disorders, pregnancy and lactation, body fluid retention, peripheral or pulmonary edema and

respiratory system infections; • No prescription of interactive medicines like Cyclosporine A and Glyburide; • Having voluntarily willingness for participation in the study; Exclusion: • Drug intolerance due to any reason; • Any severe or relatively severe side effects like increasing liver function tests (more than 3 times of baseline or 2 times of normal), anemia, severe pulmonary infection, fluid retention and edema, etc.; • Discontinuing of participation by the participants; • Irregular intake of Farantan due to any reason; • Any undesirable medical condition which urge the physicians to change the treatment.

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Research Institute of Tuberculosis and Lung Diseases
Street address
Dr Masih daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Postal code
1956944413
Approval date
2013-12-29, 1392/10/08
Ethics committee reference number
Sbmu1.REC.1392.42

Health conditions studied

1

Description of health condition studied
Pulmonary Arterial Hypertension
ICD-10 code
I27.2
ICD-10 code description
Other secondary pulmonary hypertension

Primary outcomes

1

Description
6 Minutes Walking Test (6MWT)
Timepoint
monthly up to 6 month & then every 3 months
Method of measurement
Distanse of walking in 6 minutes (in standard conditions)

Secondary outcomes

1

Description
ProBNP
Timepoint
at the begining and then every 3 months
Method of measurement
Enzyme-Linked Fluorescent Assay

2

Description
CBC
Timepoint
monthly up to 6 month & then every 3 months
Method of measurement
Autoanalyzer equipments

3

Description
Liver function test
Timepoint
monthly up to 6 month & then every 3 months
Method of measurement
Autoanalyzer equipments

Intervention groups

1

Description
Case group: Prescription of Farantan (Bosentan) tablet 125 mg, orally, twice a day, for 2 years
Category
Treatment - Drugs

2

Description

Control group: prescription of placebo, completely similar to Farantan tablet, orally, 125 mg twice a day for 2 years

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Elmira Ghashghaei Davari

Street address

Dr M. Daneshvari Hospital, Daar-Abad, Niavaran

City

Tehrran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faran Pharmaceutical Company

Full name of responsible person

Ghasemali Ashofteh

Street address

2nd floor, No 19, Parvin Street, Valiasr Ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Faran Pharmaceutical Company

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

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Dr. Kayvan Saeedfar

Position

Executive manager

Other areas of specialty/work

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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