

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

Name

Kayvan Saeedfar

Name of organization / entity

National Research Institute of Tuberculosis and Lung Diseases

Country

Iran (Islamic Republic of)

Phone

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Email address

k.saeedfar@sbmu.ac.ir

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, Tracleer 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

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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

Distance of walking in 6 minutes (in standard conditions)

Secondary outcomes**1****Description**

ProBNP

Timepoint

at the beginning 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

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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

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Full name of responsible person

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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