

# 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

##### Name

Kayvan Saeedfar

##### Name of organization / entity

National Research Institute of Tuberculosis and Lung Diseases

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2712 2012

##### 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

**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**

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

##### 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

#### Street address

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K.saeedfar@sbmu.ac.ir

#### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

National Research Institute of Tuberculosis and Lung Diseases

##### Full name of responsible person

Prof. Mohammad Reza Masjedi

##### Position

Prof. of Pulmonology

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

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##### Position

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#### Other areas of specialty/work

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**Email**

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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*