

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Comparison of Bosentan and Sildenafil in the treatment of persistent pulmonary hypertension of the newborn

#### Protocol summary

##### Study aim

Comparison the therapeutic effects of two drugs of Bosentan and Sildenafil on pulmonary artery pressure in newborns with PPHN

##### Design

This study is a clinical trial. Randomized numerical formulas using Excel has been used for randomization.

##### Settings and conduct

This study is a clinical trial. All new born with respiratory distress, decreased Sat o2 and cyanosis is admitted to the NICU of Akbarabadi and Ali Asghar hospitals, who had inclusion criteria, entered the study after parents' consent.

##### Participants/Inclusion and exclusion criteria

All newborns with respiratory distress, decreased of Sat o2 and cyanosis admitted to the NICU of Akbarabadi and Ali Asghar hospital and if the echocardiography findings are based on pulmonary artery pressure higher than or equal to 25 mmHg and the severity of tricuspid valve regurgitation higher than or equal to 30 mmHg with or without right to left shunt, after obtaining the consent of the parents entered the study. Other cyanotic heart disease rejected, there is no other cyanotic justifying disease. PPHN is not due to pneumonia or meconium aspiration.

##### Intervention groups

Newborns with PPHN treated with Bosentan tablets 1mg/kg/dose every 12 hours through PG.  
Newborns with PPHN treated with sildenafil tablet 0.4mg/kg/dose every 12 hours through PG.

##### Main outcome variables

Pulmonary artery pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190127042504N1**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **retrospective**

Last update: **2019-02-22, 1397/12/03**

Update count: **0**

##### Registration date

2019-02-22, 1397/12/03

##### Registrant information

###### Name

saba farhangdoust

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2261 7959

###### Email address

farhangdoust.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-16, 1396/03/26

##### Expected recruitment end date

2018-06-16, 1397/03/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Bosentan and Sildenafil in the treatment of persistent pulmonary hypertension of the newborn

##### Public title

Comparison of Bosentan and Sildenafil in the treatment of persistent pulmonary hypertension of the newborn

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All new borns with respiratory distress, decreased of Sat o2 and cyanossies admitted to the NICU of Akbarabadi and Ali Asghar hospital If the echocardiography findings are based on pulmonary artery pressure higher than or equal to 25 mmHg The severity of tricuspid valve regurgitation higher than or equal to 30 mmHg with or without right to left shunt Obtaining the consent of the parents

### Exclusion criteria:

Other cyanotic heart disease No other cyanotic justifying disease PPHN is not due to pneumonia or meconium aspiration

## Age

From **1 day** old to **30 days** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For randomization of the formulation used in Excel software, the coupled numbers obtained in this table will be allocated to the drug A, namely, Bosentan and the individual numbers for the drug B, Sildenafil.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The randomization is double blind. On the other hand, the neonates, according to their age and their parents, and on the other hand, the pediatric cardiologist who perform echocardiography before and after the treatment, and the analyzer has no information about the type of drug. The information for the two groups is provided as code A or B to the analyzer

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

#### Street address

Shahid Hemmat Highway, Iran University of Medical Sciences

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۳۹۶۱۴۵۳۵

### Approval date

2017-06-13, 1396/03/23

### Ethics committee reference number

IR.IUMS.FMD.REC1396.9511165012

## Health conditions studied

## 1

### Description of health condition studied

Persistent pulmonary hypertension of newborn

### ICD-10 code

I26-28

### ICD-10 code description

Persistent pulmonary hypertension

## Primary outcomes

## 1

### Description

Pulmonary artery pressure

### Timepoint

At the start of study and then 1week after

### Method of measurement

Echocardiography

## Secondary outcomes

## 1

### Description

Comparison of the duration of treatment in the two groups

### Timepoint

daily visit

### Method of measurement

Physical examination

## 2

### Description

Comparison of the duration of O2 as needed in two groups

### Timepoint

Daily visit

### Method of measurement

Pulseoximetry

### 3

#### **Description**

Comparrison of side effect in 2 groups

#### **Timepoint**

Daily visit,weekly labratory test

#### **Method of measurement**

Blood pressure,labratory

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Newborns with PPHN treated with Bosentan tablet 1mg/kg/dose every 12 hours through PG until 1 mounths

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group2 : Newborns with PPHN treated with sildenafil tablet 0.4 mg/kg/dose every 12 hours through PG until 1 mounths

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Akbar Abadi hospital and Ali asghar Children's Hospital

##### **Full name of responsible person**

Saba Farhangdoust

##### **Street address**

No, 193, Madares Highway, Dastgerdi St, Ali Asghar children's hospital

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1919816766

##### **Phone**

+98 21 2261 7957

##### **Email**

farhangdoust1980@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Kazem Malakouti

#### **Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1449614535

#### **Phone**

+98 21 8670 2503

#### **Email**

research@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Iran University of Medical Sciences

#### **Proportion provided by this source**

50

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Saba Farhangdoust

##### **Position**

Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Pediatrics

##### **Street address**

No,193, Ali Asghar Children Hospital, Dastgerdi St., Modares Highway

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## Person responsible for scientific inquiries

### Contact

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Iran University of Medical Sciences

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Saba Farhangdoust

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Resident

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## Person responsible for updating data

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Saba Farhangdoust

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Resident

**Latest degree**

Medical doctor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available