

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

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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

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1449614535

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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

Name of organization / entity

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Full name of responsible person

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Position

Resident

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Person responsible for updating data

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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