

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of Macitentan compared to Bosentan in neonates with persistent pulmonary hypertension treated with Sildenafil

Protocol summary

Study aim

Investigating the effect of Macitentan compared to Bosentan in infants with stable pulmonary hypertension treated with Sildenafil

Design

A clinical trial with parallel groups, double-blinded, randomized, phase 3 on 43 patients with persistent pulmonary hypertension of the newborn. The randomization function of Excel software was used for randomization.

Settings and conduct

This study was conducted in the NICU of Akbarabadi Hospital. Patients with persistent pulmonary hypertension of the newborn were randomly assigned to two groups. In intervention group A, neonates received Bosentan and Sildenafil. In group B, neonates received Macitentan and Sildenafil. In this study, the doctor and the researcher did not know about the type of medicine received.

Participants/Inclusion and exclusion criteria

Inclusion: 1. Newborns with respiratory symptoms, decreased arterial oxygen saturation and cyanosis
Exclusion: 1. Cyanotic heart diseases 2. Increased pulmonary artery pressure due to pneumonia or meconium aspiration

Intervention groups

Group A: Bosentan tablets with a concentration of 1 mg/kg and Sildenafil with a concentration of 0.4 mg/kg every 12 hours by PG
Group B: Macitentan tablets with a concentration of 1 mg/kg and Sildenafil with a concentration of 1 mg/kg every 12 hours by PG

Main outcome variables

Response to treatment of persistent pulmonary hypertension of the newborn

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160120026115N9**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Mandana Kashaki

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-30, 1399/10/10

Expected recruitment end date

2021-04-23, 1400/02/03

Actual recruitment start date

2021-08-01, 1400/05/10

Actual recruitment end date

2021-11-02, 1400/08/11

Trial completion date

2022-06-02, 1401/03/12

Scientific title

The effect of Macitentan compared to Bosentan in neonates with persistent pulmonary hypertension treated with Sildenafil

Public title

The effect of Macitentan compared to Bosentan in neonates with persistent pulmonary hypertension treated with Sildenafil

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parents' satisfaction to participate in the study Newborns with respiratory symptoms, decreased arterial oxygen saturation, and cyanosis Pulmonary artery pressure greater than or equal to 25 mmHg and severity of tricuspid valve failure greater than or equal to 30 mmHg with or without right-to-left shunt

Exclusion criteria:

Cyanotic heart diseases Other diseases cyanosis Increased pulmonary artery pressure due to pneumonia or meconium aspiration

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done according to the random number table using the RAND function in Excel software. The even numbers obtained in this table were assigned to drug A (Bosentan and Sildenafil) and the odd numbers to drug B (Masitentan and Sildenafil). The random list was given to the epidemiologist of the study, and each patient who entered the study was contacted by the doctor to find out whether the person entered group A or B.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs received are identical in appearance (color and size), the pills were placed in coded envelopes with the same appearance, and the patient and cardiologist did not know about the drug received.

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

Next to the Milad Tower, Hemat Highway.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.IUMS.FMD.REC.1400.168

Health conditions studied

1

Description of health condition studied

Persistent pulmonary hypertension of the newborn

ICD-10 code

P29.3

ICD-10 code description

Persistent fetal circulation

Primary outcomes

1

Description

Persistent Pulmonary Hypertension of the Newborn

Timepoint

The beginning of the study, 6 and 12 days after the intervention

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bosentan tablets (manufactured by Faran Shimi, Iran) with a concentration of 1 mg/kg and Sildenafil (Alborz Darou) with a concentration of 0.4 mg/kg every 12 hours were prescribed. The treatment was discontinued when the arterial oxygen saturation level

was higher than 95 and the Pulmonary Arterial Hypertension was lower than 25 in echocardiography and the severity of Tricuspid valve regurgitation was lower than 30.

Category

Treatment - Drugs

2**Description**

Intervention group: Macitentan tablets (Tadbir Kalaye Jam) with a concentration of 1 mg/kg and Sildenafil(Alborz Darou) with a concentration of 1 mg/kg every twelve hours were prescribed. The treatment was discontinued when the arterial oxygen saturation level was higher than 95 and the Pulmonary Arterial Hypertension was lower than 25 in echocardiography and the severity of Tricuspid valve regurgitation was lower than 30.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Akbarabadi Hospital

Full name of responsible person

Sama dabbagh

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

100

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

Sama dabbagh

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Available Information

When the data will become available and for how long

1402

To whom data/document is available

All of people

Under which criteria data/document could be used

Information

From where data/document is obtainable

Email S.dabbagh69@yahoo.com

What processes are involved for a request to access data/document

Asked from email

Comments