Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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 rand 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
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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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Molavi St, Molavi (cross)

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keyvani

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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

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Full name of responsible person

Mandana Kashaki

Position

Associate professor

Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Sama dabbagh
Position
Resident
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Specialist
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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
Avalable Information
When the data will become available and for how long
1402
To whom data/document is available
All of peaple
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