Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison effect of oral bosentan in preventing Bronchopulmonary Dysplasia (BPD) in premature infants with respiratory distress syndrome

Protocol summary

Study aim
Comparison of surfactant injection alone with simultaneous intratracheal administration of surfactant and oral bosentan in the prevention of bronchopulmonary dysplasia in premature infants with respiratory distress syndrome

Design
A controlled, parallel-group, double-blind, randomized, phase 4 clinical trial on 90 patients. A block method is used for randomization.

Settings and conduct
Premature infants with a gestational age of less than or equal to 37 weeks born during 2026 AH in the neonatal intensive care unit of Arak hospitals who have been admitted with respiratory distress syndrome and who meet the inclusion criteria and require surfactant injection will be included in the study. Infants and parents will not know the type of medication received. Also, the outcome assessor will complete the checklist based on the patient assessment without knowing the medication received.

Participants/Inclusion and exclusion criteria
Babies with a gestational age of less than or equal to 37 weeks With moderate or severe neonatal respiratory distress syndrome requiring mechanical ventilation Requires an inspiratory oxygen fraction greater than 30% Absence of severe congenital anomalies

Intervention groups
Intervention group: This group of infants will receive oral bosentan in addition to BLES surfactant. This tablet is administered at a concentration of 1 mg/kg every twelve hours for a maximum of one month. Hospitalized infants will receive a vial of BLES surfactant at a dose of 5 cc/kg intratracheally. Control group: This group will receive BLES surfactant alone at a dose of 5 cc/kg body weight.

Main outcome variables
Severity of respiratory distress at birth; need for ventilation; length of hospital stay; duration of mechanical ventilation; pneumothorax; incidence of pulmonary hemorrhage; incidence of intraventricular hemorrhage; mean airway pressure; need for subsequent doses of surfactant

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260119068615N1**
Registration date: **2026-02-14, 1404/11/25**
Registration timing: **prospective**

Last update: **2026-02-14, 1404/11/25**
Update count: **0**

Registration date
2026-02-14, 1404/11/25

Registrant information
Name
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-04-04, 1405/01/15
Expected recruitment end date
2026-10-07, 1405/07/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of oral bosentan in preventing Bronchopulmonary Dysplasia (BPD) in premature infants with respiratory distress syndrome

Public title

Effect of oral bosentan in preventing Bronchopulmonary Dysplasia (BPD) in premature infants with respiratory distress syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Babies with a gestational age of less than or equal to 37 weeks With moderate or severe neonatal respiratory distress syndrome requiring mechanical ventilation Requires an inspiratory oxygen fraction greater than 30% Absence of severe congenital anomalies

Exclusion criteria:

Severe asphyxia Cardiovascular instability shock Oral intolerance to medications The presence of drug side effects

Age

To **5 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be used to randomly assign participants. For this purpose, blocks of fixed size (e.g., blocks of 4 or 6) will be considered so that the allocation ratio between the two treatment groups remains balanced throughout the study. The order of allocation within each block will be determined using a random number table (or computer software) and will be placed as coded cards in opaque, impenetrable envelopes. As each eligible infant arrives, one envelope will be opened sequentially and the group allocation will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will not be aware of the type of medication they are receiving. Clinical caregivers will inject the medication prepared in the syringe based on the patient code. Also, the outcome assessor will complete the relevant checklist without knowing the type of intervention. The principal investigator will only be responsible for collecting the checklists and recording the information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Shahid Shiroudi Ave, Alamolhoda Ave, Amirkabir Hospital

City

Arak

Province

Markazi

Postal code

3819693181

Approval date

2025-09-07, 1404/06/16

Ethics committee reference number

IR.ARAKMU.REC.1404.172

Health conditions studied

1

Description of health condition studied

Bronchopulmonary Dysplasia

ICD-10 code

P27.1

ICD-10 code description

Bronchopulmonary dysplasia originating in the perinatal period

Primary outcomes

1

Description

Severity of respiratory distress at birth

Timepoint

Measurement periods include 1, 2, 3, 5, 7, and 10 days.

Method of measurement

Based on neonatal respiratory score

Secondary outcomes

1

Description

The need for oxygen or ventilation

Timepoint
Measurement periods include 14 and 28 days after the intervention
Method of measurement
Based on the review of diagnostic criteria in favor of bronchopulmonary

2

Description
Length of hospital stay
Timepoint
One month
Method of measurement
Counting the number of days hospitalized

3

Description
Duration of mechanical ventilation
Timepoint
After discharge
Method of measurement
Counting the days you need mechanical ventilation

4

Description
Pneumothorax
Timepoint
After discharge
Method of measurement
Chest X-ray

5

Description
Pulmonary hemorrhage
Timepoint
The time points are 14 and 28 days after the intervention.
Method of measurement
Chest X-ray

6

Description
Intraventricular hemorrhage
Timepoint
The time points are 14 and 28 days after the intervention
Method of measurement
Brain ultrasound

7

Description
Average airway pressure
Timepoint
On the first and third day of treatment
Method of measurement
Ventilator

8

Description
Need for next dose of surfactant
Timepoint
The first three days of hospitalization
Method of measurement
Patient file

Intervention groups

1

Description
Intervention group: Oral bosentan plus surfactant (BLES)
Category
Prevention

2

Description
Control group: routin treatment surfactant (BLES)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir Educational and Medical Center
Full name of responsible person
Afsaneh Akhundzadeh
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Shahid Shiroudi Ave, Nurse Square, Amirkabir Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Afsaneh Akhundzadeh
Position
Associate professor
Latest degree
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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

Not applicable