

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

Hadi Mohammadi

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

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Markazi

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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: routine 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

Arak University of Medical Sciences

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
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
Subspecialist

Other areas of specialty/work
Pediatrics

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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