Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of use of budesonide nebulizer on reducing bronchopulmonary dysplasia in preterm infants less than 32 weeks a randomized of clinical trial

Protocol summary

Study aim

Evaluate the efficacy of inhaled budesonide in preterm infants for preventing BPD. Secondary objectives were assessing its effects on the duration of respiratory support, hospital stay, the incidence of severe BPD, and mortality before 36 post-menstrual age (PMA). We also evaluated related complications

Design

Clinical trial with control group with parallel groups, Double-blind, Randomized, Phase 3 on 70 patients.

Settings and conduct

kamali hospital

Participants/Inclusion and exclusion criteria

Preterm infants (25–32 weeks GA), ≤12 hours old, requiring respiratory support, were eligible. Exclusion criteria included birth weight ≤500 g or >1500 g, major congenital anomalies, pneumothorax, or early-onset sepsis prior to randomization. All eligible infants meeting these conditions were enrolled in the study.

Intervention groups

Eligible infants received the first dose within 24 hours of birth. Inhaled budesonide or placebo (normal saline) was nebulized every 12 hours for 7 days. Delivery method depended on respiratory support type. The protocol ensured consistent dosing and full blinding across all stages, with indistinguishable appearance of both solutions.

Main outcome variables

Bronchopulmonary dysplasia/Mortality rate/Severity of Bronchopulmonary dysplasia/Need for supplemental oxygen/duration of mechanical ventilation duration of non-invasive ventilation/Intraventricular hemorrhage/Incidence of early and late onset sepsis

General information

Reason for update

Due to practical limitations encountered during the data collection process and a lower-than-anticipated number of enrolled participants, a revision of the initially estimated sample size became necessary. To obtain a more accurate and realistic estimation, the G*Power statistical software was used. The recalculation was performed based on a statistical power of 0.80, a significance level (α) of 0.05, and the expected effect size. As a result, the sample size was adjusted to reflect feasible implementation within the available resources and study conditions. This revision was made to maintain scientific rigor and ensure the generalizability and statistical validity of the study findings. The updated sample size has been reflected in the final IRCT registration. In addition, and in line with the principles of proper clinical trial design, the randomization and blinding methods used in the study were clarified and updated. These revisions were made to ensure adherence to appropriate procedures for random allocation and multi-level blinding (including physicians, data analysts, outcome assessors, and clinical staff). Detailed information was provided regarding the use of the Sealed Envelope web-based software for randomization with a 1:1 allocation ratio, as well as the procedures implemented to preserve blinding throughout all stages of the trial, including drug preparation, administration, outcome assessment, and data analysis. These updates were made to enhance scientific transparency, improve reproducibility, and strengthen the methodological quality of the trial as registered in IRCT. Moreover, to better target a high-risk neonatal population and reduce heterogeneity in the study sample, an additional exclusion criterion was introduced. Infants with a birth weight greater than 1500 grams were excluded from the study. This adjustment aimed to focus the investigation on preterm infants at higher risk for bronchopulmonary dysplasia (BPD), thereby improving the precision of the findings and their clinical relevance. This change has also been incorporated into the updated

IRCT registration.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059227N1**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**
Update count: **1**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name

Kobra Hosseini

Name of organization / entity

Alborz University of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-08-19, 1403/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of use of budesonide nebulizer on reducing bronchopulmonary dysplasia in preterm infants less than 32 weeks a randomized of clinical trial

Public title

"Effect of budesonide nebulizer on reducing BPD"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature neonates between 24 and 32 weeks

Exclusion criteria:

Weight Less than 500 grams or more than 1500 grams Neonate with fatal congenital abnormalities or disorders and congenital heart and lung diseases Pneumothorax prior to randomization clinical evidence of early onset sepsis prior to randomization

Age

To **1 day** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Once the eligibility of participants was confirmed and prospective consent obtained, infants were randomly assigned to either receive inhaled budesonide or placebo using the Sealed Envelope web-based randomization software (https://www.sealedenvelope.com) with an allocation ratio of 1:1.

Blinding (investigator's opinion)

Double blinded

Blinding description

To maintain blinding, physicians, data analysts, outcome assessors, and trial investigators were blinded to the randomization group throughout the study. The study medications were prepared by a designated clinical manager who was not involved in clinical care. Both the budesonide and placebo solutions were colorless, indistinguishable in appearance, and prepared in equal volume. The designated clinical manager labeled study medications based on the patient’s code. Outcome data were recorded by a neonatal specialist who was unaware of the administered drugs. All clinical staff, caregivers, the principal investigator and data analysts were blinded during data collection and analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Science

Street address

Alborz University of Medical Science, Official settlement, North Taleghani boulevard, Taleghani Square, Karaj, Alborz Province

City

karaj

Province

Alborz

Postal code

3147734568

Approval date

2023-09-08, 1402/06/17

Ethics committee reference number

IR.ABZUMS.REC.1402.162

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

Bronchopulmonary dysplasia

Timepoint

36 weeks PMA or discharge to home, whichever occurred first

Method of measurement

According to the NICHD2001 ,The need for supplemental oxygen at 28 PMA

2

Description

mortality

Timepoint

daily

Method of measurement

until discharge

Secondary outcomes

1

Description

The duration of hospitalization

Timepoint

Discharge Time

Method of measurement

The number of days of hospitalization records

2

Description

Duration of need for oxygen

Timepoint

Daily

Method of measurement

Days count before O2 discontinue

3

Description

duration of non-invasive ventilation

Timepoint

Day

Method of measurement

days of non-invasive ventilation

4

Description

duration of mechanical ventilation

Timepoint

daily

Method of measurement

days of mechanical ventilation

5

Description

intraventricular hemorrhage

Timepoint

daily

Method of measurement

based on cranial ultrasonography

Intervention groups

1

Description

Intervention group: treatment with inhaler Budesonide through jet nebulizer (250 mcg every 12 hours) for 7 days.

Category

Prevention

2

Description

Control group:prescribe 3 cc of 0.9% normal saline nebulizer every 12 hours for 7 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital(Karaj)

Full name of responsible person

Dr Hani Milani

Street address

KAMALI Hospital, Kamali alley, Shahid Beheshti st, Shohada Squ,

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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?
No

Title of funding source
Dr hani milani

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Kobra Hosseini

Position
Medical Intern

Latest degree
Medical doctor

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

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