Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of salbutamol nebulized on respiratory distress in term infants with transient neonatal tachypnea admitted to the NICU

Protocol summary

Study aim
Determining the effect of inhaled salbutamol on respiratory distress in term infants with transient tachypnea of the newborn admitted to the neonatal intensive care unit

Design
This study is a Phase II triple-blind randomized clinical trial designed to evaluate the efficacy and safety of inhaled salbutamol in full-term neonates with transient tachypnea of the newborn. Eligible neonates are enrolled after obtaining written parental consent and are randomly allocated into intervention and control groups using block randomization. The intervention group receives inhaled salbutamol, while the control group receives placebo. Respiratory and clinical outcomes are assessed before and after intervention, and data are analyzed using STATA software

Settings and conduct
Clinical trial – Shahid Madani Hospital and Shahid Rahimi Hospital

Participants/Inclusion and exclusion criteria
Gestational age greater than 37 weeks. Tachypnea with more than 60 breaths per minute within the first 6 hours of life. Chest X-ray findings including

Intervention groups
Intervention group A receives inhaled salbutamol (Ventolin) at a dose of 0.1 mg/kg, while the control group receives a placebo consisting of 0.1 mg/kg of distilled water.

Main outcome variables
Salbutamol Duration of tachypnea Duration of oxygen therapy Duration of assisted ventilation Time from birth to initiation of feeding Length of hospital stay Gender Oxygen saturation (%) Heart rate Respiratory rate Respiratory distress score Type of delivery Neonatal weight

General information

Reason for update
Acronym
TTN
IRCT registration information
IRCT registration number: **IRCT20250722066594N1**
Registration date: **2026-10-20, 1405/07/28**
Registration timing: **prospective**

Last update: **2026-10-20, 1405/07/28**
Update count: **0**
Registration date
2026-10-20, 1405/07/28

Registrant information
Name
Zeynab PirdadehKHani
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-23, 1405/08/01
Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of salbutamol nebulized on respiratory distress in term infants with transient neonatal tachypnea admitted to the NICU

Public title

The effect of salbutamol nebulizer on respiratory distress in term infants with transient neonatal tachypnea admitted to the NICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age is greater than 37 weeks. Tachypnea with more than 60 breaths per minute in the first 6 hours Lung radiography findings include: congestion and prominence of the navel of the lungs, flattening of the diaphragm, airiness of the lungs, pleural effusion, filling of the horizontal and oblique fissures between the lung lobes.

Exclusion criteria:

Congenital abnormalities Birth Asphyxia Meconium Aspiration Syndrome Congenital Heart Diseases Based on Echocardiography Respiratory Distress Syndrome (RDS)

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

A triple-blind, randomized clinical trial will be conducted on newborns. In the first stage, participants will be selected via purposive sampling from among those who meet the study's inclusion criteria and for whom parents have provided written informed consent. Participants will then be randomly assigned to either an intervention group or a control group using a balanced block randomization method (with a block size of four). Randomization will be performed prior to the commencement of participant recruitment; codes—designated as 'A' (intervention group) and 'B' (control group)—will be established, and their sequence determined. Specifically, the following four-item combinations will be generated: AABB, ABAB, ABBA, BABA, BBAA, and BAAB. A six-sided die (numbered 1 through 6) will then be used to randomly select these combinations, thereby establishing the allocation sequence (the allocation list) for assigning individuals to the intervention and control groups. The allocation list will be kept confidential by the physician (principal investigator). It should be noted that randomization will be performed separately for each hospital (Shahid Rahimi and Shahid Madani). Once an individual is determined by the physician (principal investigator) to be eligible for the study, they will be assigned to the appropriate group based on the allocation list. To ensure that neither the parents nor the assessor are aware of the group assignment, each study participant will be assigned a random, non-sequential four-digit number, which will be recorded in the allocation list. The physician will document this four-digit number in the participant's medical record. The team’s statistician, who is responsible for data analysis, will have no direct contact with the participants and will not be involved in data collection.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, a triple-blind design is employed (involving parents/participants, the outcome assessor, and the statistical analyst). Regarding the implementation procedure: the randomization sequence (allocation list) is generated prior to the start of the study, separately for each of the two hospitals (Shahid Rahimi and Shahid Madani). This list is kept confidential by a department supervisor—who has no involvement in recruitment, intervention, assessment, or analysis—and remains inaccessible to the recruiting physician and the assessor. Once an infant is deemed eligible by the physician (supervising faculty member) and parental consent is obtained, the infant is assigned to a group based on the next entry in the allocation list. Consequently, the physician remains unaware of the upcoming group assignment prior to determining eligibility, thereby preventing selective enrollment (allocation concealment). To ensure parental blinding, parents are not informed of their infant’s group assignment. To blind the outcome assessor, each participant is assigned a random, non-sequential four-digit code, which is recorded in the allocation list; the physician enters only this code into the patient’s medical record. Thus, when evaluating outcomes, the assessor encounters only the code, from which the intervention or control group cannot be identified. Both the intervention (inhaled salbutamol) and the control (distilled water) are prepared in identical, unlabeled vials—appearing as clear, colorless solutions—and the method of administration (nebulizer), the device used, and the duration and conditions of the procedure are identical for both groups. The preparation and delivery of the solution, based on the allocation list, are carried out by an independent nurse who is not involved in the assessment of outcomes. The outcome assessor is not present at the bedside during the intervention; instead, they assess the outcomes only after the intervention is complete, using the participant’s four-digit code. Consequently, the assessor cannot determine the participant's assigned group based on the appearance or odor of the medication, nor through the method of administration. Similarly, the statistician responsible for data analysis has no direct contact with the participants and is not involved in data collection. The analysis is performed using the four-digit codes, and the allocation list is not

made available to the statistician until the final analysis is complete. In the event of a serious adverse event that necessitates knowledge of the participant's group assignment, the blinding is broken only for that specific individual, subject to approval by the department head. بهینه‌سازی با ChatGPT

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
No. 137, Araste 5, Enghelab ., Khorramabad city

City
KHorramabad

Province
Lorestan

Postal code
1111111111

Approval date
2026-04-28, 1405/02/08

Ethics committee reference number
IR.LUMS.REC.1405.085

Health conditions studied

1

Description of health condition studied
transient neonatal tachypnea admitted

ICD-10 code
P28.5

ICD-10 code description
Respiratory failure of newborn

Primary outcomes

1

Description
Infant respiratory distress score

Timepoint
0-24

Method of measurement
Information collection form

2

Description
duration of infant hospitalization

Timepoint
0-24

Method of measurement
Information collection form

3

Description
duration of oxygen therapy

Timepoint
0-24

Method of measurement
Information collection form

4

Description
time of initiation of enteral feeding

Timepoint
0-24

Method of measurement
Information collection form

5

Description
infant oxygen saturation percentage

Timepoint
0-24

Method of measurement
Information collection form

6

Description
duration of tachypnea

Timepoint
0-24

Method of measurement
Information collection form

7

Description
Duration of oxygen therapy for infants

Timepoint
0-24

Method of measurement
Information collection form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group A receives inhaled salbutamol (Ventolin) at a dosage of 0.1 mg/kg. The salbutamol is manufactured by Shahid Ghazi Pharmaceutical Company,

with each 2.5 ml ampoule containing 2.5 mg of salbutamol.

Category
Treatment - Drugs

2

Description
Control group B receives a placebo consisting of 0.1 mg/kg of distilled water; 5 mL vials of distilled water produced by Shahid Ghazi Pharmaceutical Company were used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rahimi Hospital, Khorramabad

Full name of responsible person
DR. GHobad Heydari

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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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?
No

Title of funding source
Personal

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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Zeynab PirdadehKHani

Position
Doctor

Latest degree
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Other areas of specialty/work
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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