Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of inhaled salbutamol (Ventolin) in the improvement of the treatment of neonatal transient tachypnea

Protocol summary

Study aim
To evaluate the effect of inhaled salbutamol on transient tachypnea of the newborn

Design
Randomized, double blind, controlled clinical trial with parallel groups, phase 2; sample size of 80 neonates. Allocation ratio 1:1 using block randomization with blocks of four. The sequence will be generated by a computer based random number generator (RANDINT), and allocation will be performed in blocks.

Settings and conduct
neonatal intensive care unit, Shahid Beheshti Hospital, Kashan, 2025. After consent, eligible neonates are block randomized one to one to inhaled salbutamol or 0.9 percent normal saline plus standard care. Double blind: coded, identical vials; parents, clinical staff and outcome assessors blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Term, near term or post term neonates; clinical signs and history of transient tachypnea of the newborn; at least one radiologic criterion such as pulmonary hyperinflation, bilateral perihilar vascular prominence or fluid in the transverse fissure. Exclusion criteria: Meconium aspiration; respiratory distress syndrome; congenital pneumonia; polycythemia; hypoglycemia; proven early onset sepsis; congenital heart disease; tachycardia above 180 beats per minute; arrhythmia; congenital anomalies.

Intervention groups
Intervention: One dose of inhaled salbutamol (Ventolin, Cipla, India) 0.15 milligram equal to 0.15 milliliter per kilogram, nebulized over 20 minutes. Control: 0.9 percent normal saline 0.15 milliliter per kilogram, nebulized over 20 minutes. Both groups receive standard neonatal intensive care.

Main outcome variables
Primary outcome variables: Anderson–Silverman respiratory distress score; respiratory rate per minute; oxygen saturation; need for supplemental oxygen; length of hospital stay.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250811066816N1**
Registration date: **2025-08-28, 1404/06/06**
Registration timing: **prospective**

Last update: **2025-08-28, 1404/06/06**
Update count: **0**

Registration date
2025-08-28, 1404/06/06

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-26, 1404/07/04

Expected recruitment end date
2025-12-25, 1404/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of inhaled salbutamol (Ventolin) in the improvement of the treatment of neonatal transient tachypnea

Public title
Effect of salbutamol on neonatal transient tachypnea

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Neonates with gestational age at term, near-term, or post-term Presence of clinical manifestations and history suggestive of TTN At least one radiologic criterion of TTN, including:Pulmonary hyperinflationBilateral perihilar vascular prominenceFluid in the transverse fissureOr similar findings

Exclusion criteria:
History of meconium aspiration Respiratory distress syndrome (RDS) Congenital pneumonia Polycythemia Hypoglycemia Proven early-onset sepsis Congenital heart disease Tachycardia exceeding 180 beats per minute Cardiac arrhythmia Congenital anomalies

Age
To **28 days** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The primary method of randomization is block randomization with an allocation ratio of 1:1. Block size is set at four, and six balanced sequences are used: AABB, BBAA, BABA, ABAB, BAAB, ABBA (A = salbutamol intervention, B = normal saline control). Each subsequent block is randomly selected with equal probability to maintain balance throughout the recruitment process. Unit of randomization: The unit of randomization is the individual neonate. A total of 80 eligible neonates, after obtaining informed consent, will be randomly assigned to one of the two groups. Randomization tool: Block sequences are generated using a computer-based random number generator (RANDINT function). Generation of the random sequence: First, all possible balanced sequences for four-patient blocks (the six sequences listed above) are defined. Then, using the RANDINT function, a long sequence of block indices is generated with equal probability (repetition of blocks allowed) until the required number for 80 participants is covered. After confirming eligibility criteria, recording baseline variables, and obtaining consent, neonates will be assigned to either the intervention or control group according to the block sequence. The study is double-blind: participants (neonates) and their parents, clinical staff, and outcome assessors are blinded. Nebulized solutions of salbutamol (Astalin/Cipla) and 0.9% normal saline are identical in appearance, volume (0.15 ml/kg), container, and labeling, and are identified only by code.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed as a double-blind trial. Neonates and their parents are allocated to either the intervention or control group based on the block randomization system, which is purely statistical. The principal investigator is aware of the group assignment of each neonate. Outcome assessors and clinical caregivers are provided with a specific code for each neonate and are instructed regarding which vial should be administered. The vials are completely identical in appearance, volume, and packaging, without any identifying labels, and are distinguished only by code. The investigator informs the assessors which coded vial should be administered to each neonate.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address
Kashan university of medical science., Pezeshk Blvd., Qotb Blvd.

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Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2025-07-27, 1404/05/05

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1404.090

Health conditions studied

1

Description of health condition studied
Transient Tachypnea of newborn

ICD-10 code
P22.1
ICD-10 code description
Transient tachypnea of newborn

Primary outcomes

1

Description
Respiratory distress score
Timepoint
Before treatment and after treatment at intervals of 30 minutes, one hour, and four hours
Method of measurement
This system is a clinical tool for assessing the severity of respiratory distress in neonates. It evaluates five main indicators: grunting, nasal flaring, xiphoid retraction, lower chest retraction, and upper chest retraction.Method of measurement: Each indicator is evaluated by direct clinical observation of a trained physician or nurse, including the presence or absence of sounds such as grunting with a stethoscope, assessment of nasal wing movements, and observation and palpation of chest wall movements in different regions during inspiration and expiration.Scoring system: For each of the five indicators, the severity of findings is scored from 0 to 2.Score 0: No sign or normal condition (for example, no grunting, no retraction).Score 1: Mild or minimal finding (for example, grunting audible with stethoscope, slight retraction or nasal flaring).Score 2: Clear or severe finding (for example, grunting audible without stethoscope, marked nasal flaring, severe chest retraction with see-saw breathing).Final interpretation: The total score ranges from 0 to 10. Lower scores indicate mild or absent respiratory distress, while higher scores represent more severe distress requiring further intervention.

Secondary outcomes

1

Description
Length of Hospital Stay
Timepoint
At admission and at discharge
Method of measurement
Based on the patient’s medical records

2

Description
Respiratory Rate
Timepoint
Before starting treatment, 30 minutes, one hour, and four hours after
Method of measurement
Counting the respiratory rate for one minute based on abdominal and chest movements of the neonate

3

Description
Heart rate
Timepoint
Before starting treatment, 30 minutes, one hour, and four hours after
Method of measurement
Based on pulse oximetry information

4

Description
Oxygen saturation
Timepoint
Before starting treatment, 30 minutes, one hour, and four hours after
Method of measurement
Based on pulse oximetry information

Intervention groups

1

Description
intervention group: they will receive a single dose of inhaled salbutamol (Ventolin, manufactured by Cipla, India) at a dose of 0.15 milligram equivalent to 0.15 milliliter per kilogram of body weight, administered by nebulizer over 20 minutes.
Category
Treatment - Drugs

2

Description
The control group: They will receive 0.9 percent normal saline at the same volume by nebulizer. Both groups will simultaneously receive standard neonatal intensive care.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital, Kashan
Full name of responsible person
Hamed Pahlavani
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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?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Foruhari
Position
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Latest degree
Medical doctor
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Title and more details about the data/document

Patient files with de-identified information, ensuring that the identity of participants is not traceable, will be available alongside the informed consent forms. Clinical reports will also be accessible, and all files can be obtained upon request by contacting the corresponding author via email.

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of academic and scientific researchers

Under which criteria data/document could be used

Non - commercial use will be approved.

From where data/document is obtainable

Send the request to corresponding author via email M.Forouhari@kaums.ac.ir

What processes are involved for a request to access data/document

Assessment of requests by corresponding author in 1 month - sending requested files via email if the request is valid.

Comments