

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

mohamad mehdi foruhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 8328

Email address

mehdi.foruhari@gmail.com

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	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.
Scientific title Investigating the effect of inhaled salbutamol (Ventolin) in the improvement of the treatment of neonatal transient tachypnea	Blinding (investigator's opinion) Double blinded
Public title Effect of salbutamol on neonatal transient tachypnea	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.
Purpose Treatment	Placebo Used
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 hyperinflation Bilateral perihilar vascular prominence Fluid in the transverse fissure Or 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	Assignment Parallel
Age To 28 days old	Other design features
Gender Both	Secondary Ids empty
Phase 1-2	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. City Kashan Province Isfahan Postal code 8715988141 Approval date 2025-07-27, 1404/05/05 Ethics committee reference number IR.KAUMS.MEDNT.REC.1404.090
Groups that have been masked • Participant • Care provider • Outcome assessor	Health conditions studied 1 Description of health condition studied Transient Tachypnea of newborn
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	

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

Street address

Pezeshk Blvd., Qotb Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5544 2015

Email

H.pahlavani@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Pezeshk Blvd., Qotb Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5544 2015

Email

g.hamidi@kaums.ac.ir

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

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Pezeshk Blvd., Qotb Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5544 2015

Email

M.Forouhari@kaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Foruhari

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Pezeshk Blvd., Qotb Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5544 2015

Email

M.Forouhari@kaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Mahdi Foruhari

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Pezeshk Blvd., Qotb Blvd.

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5544 2015

Email

M.Forouhari@kaums.ac.ir

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	obtained upon request by contacting the corresponding author via email.
Statistical Analysis Plan	When the data will become available and for how long
No - There is not a plan to make this available	6 months after publication
Informed Consent Form	To whom data/document is available
Undecided - It is not yet known if there will be a plan to make this available	All of academic and scientific researchers
Clinical Study Report	Under which criteria data/document could be used
Yes - There is a plan to make this available	Non - commercial use will be approved.
Analytic Code	From where data/document is obtainable
No - There is not a plan to make this available	Send the request to corresponding author via email
Data Dictionary	M.Forouhari@kaums.ac.ir
No - There is not a plan to make this available	What processes are involved for a request to access data/document
Title and more details about the data/document	Assessment of requests by corresponding author in 1 month - sending requested files via email if the request is valid.
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	Comments