

# 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

##### 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

### 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 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

### 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.

##### 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

## 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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Pezeshk Blvd., Qotb Blvd.

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##### Phone

+98 31 5544 2015

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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

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Pezeshk Blvd., Qotb Blvd.

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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

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## Person responsible for scientific inquiries

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**Position**

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

Pediatrics

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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**