

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

### The comparison of inhaled salbutamol in two different doses and placebo on Transient tachypnoea of newborn

#### Protocol summary

##### Study aim

Determining the effect of inhaled salbutamol on treatment of Transient tachypnoea of newborn

##### Design

A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 90 children with transient tachypnoea, using [www.sealedenvelope.com](http://www.sealedenvelope.com) for randomization.

##### Settings and conduct

This study is performed in Firoozabadi and Akabarabadi Hospital. Newborns with tachypnea are randomly assigned into three groups. In the first and second intervention groups, newborns receive inhaled salbutamol. In the control group, newborns receive normal saline. In this study, participants and physicians did not know the type of medication they received.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of TTN is based on the criteria of respiratory distress less than 6 hours after birth (respiration rate more than 60 breaths per minute, grunting, nasal flaring or retraction, cyanosis) and known findings on X-ray (fluid in minor fissures, hyperventilation, prominent central vascular markings, flattening of the diaphragm, increased anterior-posterior diameter, bilateral perihilar congestion). Non-inclusion criteria: Meconium aspiration, other known causes of tachypnea in infants such as (RDS, PPHN, pneumonia, meconium aspiration, premature sepsis of infants, polycythemia, hypocalcemia, hypoglycemia), Abnormal auscultation (Murmur) during cardiac examination

##### Intervention groups

In the first and second intervention groups, newborns receive inhaled salbutamol through a nebulizer at a dose of 1.25 and 2.5 mg/kg respectively. In the third group, newborns receive normal saline.

##### Main outcome variables

Tachypnea duration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190328043133N1**

Registration date: **2023-03-12, 1401/12/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-12, 1401/12/21**

Update count: **0**

##### Registration date

2023-03-12, 1401/12/21

##### Registrant information

##### Name

Farhad Abolhasan Choobdar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2283 9368

##### Email address

choobdar.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-22, 1401/09/01

##### Expected recruitment end date

2023-04-21, 1402/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                      |                                                                                    |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| The comparison of inhaled salbutamol in two different doses and placebo on Transient tachypnoea of newborn |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | preparing raw materials, but will not have a role in the process of conducting the study directly and recording data. The NICU resident physician and nurse will be responsible for conducting the study and will not know the contents of the vials |                                                                                    |
| <b>Public title</b>                                                                                        | The effect of inhaled salbutamol on treatment of Transient tachypnoea of newborn                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Placebo</b>                                                                                                                                                                                                                                       | Used                                                                               |
| <b>Purpose</b>                                                                                             | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Assignment</b>                                                                                                                                                                                                                                    | Parallel                                                                           |
| <b>Inclusion/Exclusion criteria</b>                                                                        | <p><b>Inclusion criteria:</b></p> <p>Consent of the infant's parents to participate in the study<br/> Minimum gestational age of 35 weeks<br/> Diagnosis of TTN is based on the criteria of respiratory distress less than 6 hours after birth (respiration rate more than 60 breaths per minute, grunting, nasal flaring or retraction, cyanosis) and known findings on X-ray (fluid in minor fissures, hyperventilation, prominent central vascular markings, flattening of the diaphragm, increased anterior-posterior diameter, bilateral perihilar congestion). Weight more than 2 kg</p> <p><b>Exclusion criteria:</b></p> <p>Meconium aspiration<br/> Other known causes of tachypnea in infants such as (RDS, PPHN, pneumonia, meconium aspiration, premature sepsis of infants, polycythemia, hypocalcemia, hypoglycemia)<br/> Abnormal auscultation (Murmur) during cardiac examination<br/> Tachycardia (number of heart rate more than 180 per minute) or arrhythmia<br/> Asphyxia<br/> Incidence of drug reactions (tremor, hypoglycemia, hypokalemia, increase in blood pressure, tachycardia and arrhythmia)</p> | <b>Other design features</b>                                                                                                                                                                                                                         |                                                                                    |
| <b>Age</b>                                                                                                 | From <b>1 day</b> old to <b>28 days</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Secondary Ids</b>                                                                                                                                                                                                                                 | empty                                                                              |
| <b>Gender</b>                                                                                              | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committees</b>                                                                                                                                                                                                                             |                                                                                    |
| <b>Phase</b>                                                                                               | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                                                                                                                                                                                                             |                                                                                    |
| <b>Groups that have been masked</b>                                                                        | <ul style="list-style-type: none"> <li>Participant</li> <li>Care provider</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Ethics committee</b>                                                                                                                                                                                                                              |                                                                                    |
| <b>Sample size</b>                                                                                         | Target sample size: <b>90</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Name of ethics committee</b>                                                                                                                                                                                                                      | Ethics committee of Iran University of Medical Sciences                            |
| <b>Randomization (investigator's opinion)</b>                                                              | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Street address</b>                                                                                                                                                                                                                                | Iran University of Medical Sciences; Next to the Milad Tower; Hemmat Highway       |
| <b>Randomization description</b>                                                                           | The randomization list was obtained from <a href="https://www.sealedenvelope.com">https://www.sealedenvelope.com</a> by the Block Randomization method. To prepare a random list, equal blocks of 6 are used so that the number of samples is the same in all three arms of the study. Babies are equally assigned to three groups A, B, and C with an equal number of patients.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>City</b>                                                                                                                                                                                                                                          | Tehran                                                                             |
| <b>Blinding (investigator's opinion)</b>                                                                   | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Province</b>                                                                                                                                                                                                                                      | Tehran                                                                             |
| <b>Blinding description</b>                                                                                | In the pharmaceutical company, the vials will be filled with salbutamol 1.25, 2.5 mg and normal saline 0.9% with the same volume and similar vials, and group A, B, and C labels will be placed on the vials. In this study, the only person who will know the content inside the vial is the neonatal specialist assistant. The neonatal specialist assistant has a role in allocating the randomized list and                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Postal code</b>                                                                                                                                                                                                                                   | 1449614535                                                                         |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Approval date</b>                                                                                                                                                                                                                                 | 2022-11-12, 1401/08/21                                                             |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Ethics committee reference number</b>                                                                                                                                                                                                             | IR.IUMS.FMD.REC.1401.413                                                           |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Health conditions studied</b>                                                                                                                                                                                                                     |                                                                                    |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                                                                                                                             |                                                                                    |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Description of health condition studied</b>                                                                                                                                                                                                       | Transient tachypnoea of newborn                                                    |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>ICD-10 code</b>                                                                                                                                                                                                                                   | P22.1                                                                              |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>ICD-10 code description</b>                                                                                                                                                                                                                       | Transient tachypnea of newborn                                                     |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Primary outcomes</b>                                                                                                                                                                                                                              |                                                                                    |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>1</b>                                                                                                                                                                                                                                             |                                                                                    |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Description</b>                                                                                                                                                                                                                                   | Tachypnea duration                                                                 |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Timepoint</b>                                                                                                                                                                                                                                     | Before the intervention, 30 minutes, 60 minutes and 4 hours after the intervention |
|                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Method of measurement</b>                                                                                                                                                                                                                         | using a watch                                                                      |

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: In this group, infants receive inhaled salbutamol at a dose of 1.25 mg/kg through a nebulizer for 10 minutes.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: In this group, infants receive inhaled salbutamol at a dose of 2.5 mg/kg of weight through a nebulizer for 10 minutes.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: In this group, infants receive 0.9% normal saline through a nebulizer for 10 minutes

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Firoozabadi hospital

##### Full name of responsible person

Rezvan Ashkanipoor

##### Street address

Before Shahre Ray Square; Fadaian Islam Street, Shahre-rey

##### City

Tehran

##### Province

Tehran

##### Postal code

1849794113

##### Phone

+98 21 4055 6434

##### Email

hospfa@iums.ac.ir

##### Web page address

<https://hospfa.iums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Akbarabadi Hospital

##### Full name of responsible person

Tehran

##### Street address

Baghe Ferdos bus station; Molavi Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1168743514

##### Phone

+98 21 5560 6034

##### Email

akbarabadihosp@yahoo.com

##### Web page address

<https://cрта.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Hosein Keyvani

##### Street address

Next to the Milad tower; Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 2503

##### Email

keivani.h@iums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Farhad Abolhasan Choobdar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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Tehran

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choobdar.f@iums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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Farhad Abolhasan Choobdar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Street address**

Aliasgar hospital; Zafar street

**City**

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**Province**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Farhad Abolhasan Choobdar

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Aliasgar hospital; Zafar street

**City**

Tehran

**Province**

Tehran

**Postal code**

1919816766

**Phone**

+98 21 2283 9368

**Fax**

**Email**

choobdar.f@iums.ac.ir

## 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