

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 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 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	
Public title	The effect of inhaled salbutamol on treatment of Transient tachypnoea of newborn	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Consent of the infant's parents to participate in the study Minimum gestational age of 35 weeks 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 Exclusion 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 Tachycardia (number of heart rate more than 180 per minute) or arrhythmia Asphyxia Incidence of drug reactions (tremor, hypoglycemia, hypokalemia, increase in blood pressure, tachycardia and arrhythmia)	Other design features	
Age	From 1 day old to 28 days old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Care provider	Ethics committee	
Sample size	Target sample size: 90	Name of ethics committee	Ethics committee of Iran University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Iran University of Medical Sciences; Next to the Milad Tower; Hemmat Highway
Randomization description	The randomization list was obtained from https://www.sealedenvelope.com 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.	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
Blinding description	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	Postal code	1449614535
		Approval date	2022-11-12, 1401/08/21
		Ethics committee reference number	IR.IUMS.FMD.REC.1401.413
		Health conditions studied	
		1	
		Description of health condition studied	Transient tachypnoea of newborn
		ICD-10 code	P22.1
		ICD-10 code description	Transient tachypnea of newborn
		Primary outcomes	
		1	
		Description	Tachypnea duration
		Timepoint	Before the intervention, 30 minutes, 60 minutes and 4 hours after the intervention
		Method of measurement	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://crtai.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

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1449614535

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+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

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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