Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 21 2283 9368

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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

Public title

The effect of inhaled salbutamol on treatment of Transient tachypnoea of newborn

Purpose

Treatment

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 drug reactions(tremor, hypoglycemia, hypokalemia, increase in blood pressure, tachycardia and arrhythmia)

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Double blinded

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 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

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences; Next to the Milad Tower; Hemmat Highway

City

Tehran

Province

Tehran

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
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Postal code
1849794113
Phone
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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
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Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
akbarabadihosp@yahoo.com
Web page address
https://crta.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Person responsible for updating data

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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