Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of nebulized Salbutamol versus nebulized Epinephrine in treatment of transient tachypnea of neonates in neonatal intensive care unit

Protocol summary

Study aim

Determining the effect of nebulized salbutamol versus nebulized epinephrine in treatment of transient tachypnea of neonates in neonatal intensive care unit

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 180 patients. Sealed envelopes were used for randomization.

Settings and conduct

Infants diagnosed with transient tachypnea will be evaluated in the neonatal intensive care unit in Al-Zahra hospital of Tabriz city. The clinical expert evaluating the results of the study and the person analyzing the study data are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria were transient tachypnea of neonates and admission at neonatal intensive care unit. Neonates with first minute apgar below 4, respiratory distress syndrome caused by surfactant deficiency, congenital anomalies, syndromes of chromosomal disorders, congenital heart diseases, premature neonatal sepsis, meconium aspiration and infants with metabolic disorders will excluded.

Intervention groups

Intervention group 1: In the salbutamol group, salbutamol nebulizer will be prescribed with a dose of 0.15 mg per kilogram of body weight of infants. Intervention group 2: In the epinephrine group, 0.5 ml per kilogram of the infants weight will be prescribed from a 1 mg/ml ampoule of epinephrine. Control group: 2 ml of normal saline will be nebulized.

Main outcome variables

Oxygen saturation

General information

Reason for update

Subject: Request for Correction of Trial Registration Information in the IRCT Registry (IRCT20221028056324N1) Dear Sir/Madam, We would like to inform you that some inconsistencies were inadvertently introduced in the initially registered information of the clinical trial with registration number IRCT20221028056324N1. As the study has now been completed, and in order to ensure full alignment of the registry entry with the approved protocol, the final manuscript, and international standards (ICMJE and CONSORT), we kindly request that the following corrections be considered and applied. 1. Correction of Primary and Secondary Outcomes At the time of initial registration, several physiological variables, including oxygen saturation (SpO_2), respiratory rate (RR), heart rate (HR), and fraction of inspired oxygen (FiO_2), were inadvertently entered under the primary outcomes section. In addition, the designated field for secondary outcomes was left incomplete due to a clerical oversight. However, the study protocol from the outset prespecified a single primary outcome: Primary outcome: Change in oxygen saturation percentage (SpO_2) This outcome was also used for the sample size calculation. All other physiological variables and clinical endpoints were predefined as secondary outcomes, as listed below: Primary outcome: Oxygen saturation (SpO_2) Secondary outcomes: Respiratory rate; Heart rate; FiO_2; Number of nebulizer administrations; Duration of NCPAP support (days); Time to first enteral feeding (hours); Time to full enteral feeding (days); Duration of supplemental oxygen (days); Length of hospital stay (days) We kindly request that the primary and secondary outcomes be corrected in the registry accordingly. 2. Correction of Sample Size At the time of initial IRCT registration, a provisional minimum sample size of 90 neonates (30 per group) was entered. Prior to trial initiation and before any participant enrollment or randomization, the required sample size was recalculated using more precise data from the study by Babaei et al. (1). Based on oxygen saturation data:

The required sample size was calculated as 46 neonates per group (α = 0.05, power = 80%). Allowing for 30% attrition, the final sample size was increased to 60 neonates per group (180 neonates in total). This scientifically justified revision was implemented prior to participant recruitment and did not introduce any risk of bias. We kindly request that the sample size be updated accordingly in the registry. 3. Correction of Trial Registration and Recruitment Timing There is an ambiguity in the timing section of the registry entry that has resulted in the study being displayed as “registered while recruiting,” whereas the trial was prospectively registered and conducted. The correct sequence of events is as follows: Ethics approval: 03 October 2022 IRCT registration approval: 09 September 2023 Estimated recruitment start date recorded in the registry: 01 September 2023 Actual start of recruitment and intervention: 02 October 2023 The date of 01 September 2023 recorded in the registry represents only an estimated recruitment start date entered during preregistration and does not reflect the actual initiation of participant enrollment. No participants were enrolled prior to trial registration. We kindly request that the actual recruitment start date be corrected so that the study is appropriately classified as prospectively registered. 4. Update of Recruitment Status As participant recruitment and follow-up have been fully completed, the recruitment status of the study has been updated to Completed. We kindly ask for confirmation of this final status, if required. We sincerely appreciate your time and cooperation in correcting the registry information and in supporting transparency and accuracy in clinical trial reporting. Thank you very much for your kind assistance. Sincerely, Dr. Nazila Khanzadeh Principal Investigator and Trial Registrant Email: Lotfalinezhadm@gmail.com Contact number: +98 914 400 5440 Reference Babaei H, Dabiri S, Mohammadi Pirkashani L, Mohsenpour H. Effects of Salbutamol on the Treatment of Transient Tachypnea of the Newborn. Iranian Journal of Neonatology. 2019;10(1):42–49.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221028056324N1**
Registration date: **2023-09-09, 1402/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-14, 1404/09/23**
Update count: **1**

Registration date

2023-09-09, 1402/06/18

Registrant information

Name

Nazila Khanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3386 0108

Email address

lotfalinezhadm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-29, 1402/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nebulized Salbutamol versus nebulized Epinephrine in treatment of transient tachypnea of neonates in neonatal intensive care unit

Public title

Effect of nebulized Salbutamol versus Epinephrine in treatment of transient tachypnea of neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Transient tachypnea of neonates Neonatal intensive care unit

Exclusion criteria:

First minute apgar below 4 Respiratory distress syndrome caused by surfactant deficiency Congenital anomalies Syndromes of chromosomal disorders Congenital heart diseases Premature neonatal sepsis Meconium aspiration Infants with metabolic disorders

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of the study groups will be done using a sealed envelope. Patients will be evaluated in three groups including intervention group 1, intervention group 2 and control group. 90 envelopes in three groups of A, B or C will prepared (30 each) and sealed. Then when the patients arrive at the neonatal intensive care unit, the envelopes are opened by the nurse delivering the patient and The grouping will be written as A, B or C on the clinical file. Then, according to the desired group, the intervention will be prescribed for the patients.

Blinding (investigator's opinion)

Single blinded

Blinding description
The specialist that evaluating the final effect of the intervention and possible complications as well as the person analyzing the data will be blinded to the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Mardaniazar Hospital, Khavaran Town
City
Tabriz
Province
East Azarbaijan
Postal code
5143377505
Approval date
2022-10-03, 1401/07/11
Ethics committee reference number
IR.TBZMED.REC.1401.601

Health conditions studied

1

Description of health condition studied
Transient Tachypnea of Neonates
ICD-10 code
P22.1
ICD-10 code description
Transient tachypnea of newborn

Primary outcomes

1

Description
Oxygen saturation
Timepoint
Half an hour, one hour and four hours after nebulizer administration
Method of measurement
Noninvasive Pulse Oximeter

Secondary outcomes

1

Description
Heart rate
Timepoint
Half an hour, one hour and four hours after nebulizer administration
Method of measurement
Physical Examination

2

Description
Respiratory rate
Timepoint
Half an hour, one hour and four hours after nebulizer administration
Method of measurement
Physical examination

3

Description
Fraction of Inspired Oxygen
Timepoint
Half an hour, one hour and four hours after nebulizer administration
Method of measurement
Pulse Oximeter

4

Description
Number of nebulizer administrations
Timepoint
During hospitalization in the neonatal intensive care unit, from admission to discharge.
Method of measurement
The number of nebulizer administrations will be obtained by counting documented nebulization events in medical records and treatment charts.

5

Description
Duration of NCPAP respiratory support (days)
Timepoint
The total duration of nasal continuous positive airway pressure (NCPAP) respiratory support, calculated from initiation to complete discontinuation, measured in days.
Method of measurement
During hospitalization in the neonatal intensive care unit, from initiation of NCPAP until complete discontinuation.

6

Description
Time to first enteral feeding (hours)
Timepoint
From birth until initiation of the first enteral feeding.
Method of measurement
Calculated based on the recorded time of birth and the documented time of initiation of the first enteral feeding in medical records.

7

Description
Time to full enteral feeding (days)
Timepoint
From birth until achievement of full enteral feeding.
Method of measurement
Calculated based on the recorded time of birth and the documented time at which full enteral feeding was achieved in medical records.

8

Description
Duration of supplemental oxygen (days)
Timepoint
During hospitalization, from initiation of oxygen therapy until complete discontinuation.
Method of measurement
Calculated based on documented start and end times of oxygen therapy in the neonate’s medical records in days.

9

Description
Length of hospital stay (days)
Timepoint
At the time of hospital discharge.
Method of measurement
Days

Intervention groups

1

Description
Intervention group 1: In the salbutamol group, salbutamol nebulizer will be prescribed with a dose of 0.15 mg per kilogram of body weight of infants.
Category
Treatment - Drugs

2

Description
Intervention group 2: In the epinephrine group, 0.5 ml per kilogram of the infants weight will be prescribed from a 1 mg/ml ampoule of epinephrine.
Category
Treatment - Drugs

3

Description
Control group: 2 ml of normal saline will be nebulized.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mardaniazar hospital
Full name of responsible person
Nazila Khanzadeh
Street address
Mardaniazar Hospital, Khavaran Town
City
Tabriz
Province
East Azarbaijan
Postal code
5143377505
Phone
+98 41 3159 5090
Email
mardaniazar@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Khosro Adibkia
Street address
3rd Floor, Central building, Faculty of medicine, Daneshgah Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3335 7310
Email
adibkia@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

Tabriz University of Medical Sciences
Full name of responsible person
Nazila Khanzadeh
Position
Neonatal specialist assistant
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
No.5, Pamchal Alley, Golha Blvd., Golshahr Street, Tabriz
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Position
Neonatal specialist assistant
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Neonatal specialist assistant
Latest degree
Specialist
Other areas of specialty/work
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Fax
Email
Lotfalinezhadm@gmail.com

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
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.
When the data will become available and for how long
Access to study data after publication of the result is available in the journal.
To whom data/document is available
Anyone interested in using the data can access the study data.
Under which criteria data/document could be used
Study data can be used for comparison with other results.
From where data/document is obtainable
Refer to the study's scientific or public accountability person for data. Dear researchers can access the data in a limited and coded manner, after completing the project end and acceptance of the scientific article, by sending a data access request from the accredited research centers with coordination with the university research committee.
What processes are involved for a request to access data/document
Refer to the study's scientific or public accountability person for data. Dear researchers can access the data in a limited and coded manner, after completing the project end and acceptance of the scientific article, by sending a

data access request from the accredited research centers with coordination with the university research committee.

Comments