

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 be 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 (SpO₂), respiratory rate (RR), heart rate (HR), and fraction of inspired oxygen (FiO₂), 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 (SpO₂) 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 (SpO₂) Secondary outcomes: Respiratory rate; Heart rate; FiO₂; 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 ($\alpha = 0.05$, 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

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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

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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,
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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Nazila Khanzadeh

Position

Neonatal specialist assistant

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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

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

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centers with coordination with the university research

committee.
Comments