Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Ventolin nebulizer with supportive treatment in Transient tachypnea of the newborns (TTN) admitted to the neonatal intensive care unit (NICU) of Imam Khomeini and Bouali Sari hospitals of Sari

Protocol summary

Study aim

The aim of this study is to compare Ventolin nebulizer with supportive treatment in transient respiratory rate of newborns and different intensities of their respiratory distress

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 0 on 60 patients randomized by Stratified Permuted Block Randomization method with blocks of 4

Settings and conduct

This double-blind randomized clinical trial is conducted in infants with TTN hospitalized in the NICU of Imam and Boali Hospitals of Sari. Patients are randomly selected by the Stratified Permuted Block Randomization method with blocks of 4 and divided into two intervention and control groups in parallel. Patients and nurses will not know about the allocation of patients to study groups.

Participants/Inclusion and exclusion criteria

Neonates with gestational age >34 weeks who meet the criteria for TTN are included in the study. In case of meconium aspiration, pneumonia, complex Coronary heart disease (CHD), Tachycardia above 180, Silverman Anderson score less than 46, Ventilator therapy since birth, diagnosis of RDS during hospitalization and administration of surfactant, they are excluded.

Intervention groups

In the intervention group, 0.1 mL of salbutamol (Ventolin, salbutamol sulfate 5 mg/mL) is nebulized in 3 mL of 0.9% normal saline. The standard dose of salbutamol is 0.15 mg/kg/dose. It will be nebulized every day with a jet-type nebulizer with a continuous oxygen flow of 5 liters per minute during a 10-minute period and every 6 hours for a day. In the control group, they will receive 2 mL of 0.9% saline as a nebulizer.

Main outcome variables

Primary outcomes: duration of initial CPAP and oxygen therapy; O2 and CO2 after nebulizer; Hospitalization days; Time to start feeding based on Silverman Anderson score I<4; stabilization of heart rate, breathing and Spo2; Absence of abdominal distension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091201002801N6**
Registration date: **2023-07-23, 1402/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-23, 1402/05/01**
Update count: **0**

Registration date

2023-07-23, 1402/05/01

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Ventolin nebulizer with supportive treatment in Transient tachypnea of the newborns (TTN) admitted to the neonatal intensive care unit (NICU) of Imam Khomeini and Bouali Sari hospitals of Sari

Public title
Comparison of Ventolin nebulizer with supportive treatment in Transient tachypnea of the newborns (TTN) admitted to the neonatal intensive care unit (NICU) of Imam Khomeini and Bouali Sari hospitals of Sari
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Neonates with gestational age more than 34 weeks Tachypnea with or without cyanosis Respiratory distress Chest X-ray findings in favor of TTN
Exclusion criteria:
Meconium aspiration Other diseases in the radiography such as pneumonia and... Complex Coronary heart disease (CHD) Tachycardia above 180 Silverman Anderson score less than 46 Ventilator therapy since birth Diagnosis of RDS during hospitalization Administration of surfactant with diagnosis of RDS
Age
From **1 year** old to **30 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of patients into two treatment groups will be by Stratified Permuted Block Randomization method with blocks of 4. First the patients are divided into two groups based on the severity of TTN, then in each group, using Block Randomization, the patients will receive one of the interventions. To generate random allocation, the sealed envelope site was used, which created the a random table with the code 105487821465911 for us, which shows how patients enter the two intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The nurse and the study participants do not know who is in which group. Placebo and drug have the same color and shape in appearance and are coded by the researcher and each patient will be given a drug code. Then the mediation is given to the nurse and nebulized.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for Research, Moallem square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4712855689
Approval date
2023-07-12, 1402/04/21
Ethics committee reference number
IR.MAZUMS.REC.1402.166

Health conditions studied

1

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

Primary outcomes

1

Description
Primary CPAP (continuous positive airway pressure) duration
Timepoint
Time interval from start to end of CPAP
Method of measurement
Minute and hour

2

Description
Oxigen therapy duration
Timepoint

Time interval from start to end of Oxigen therapy

Method of measurement

Minute and hour

3

Description

Hospitalization length

Timepoint

Time from hospitalization to discharge

Method of measurement

Day

4

Description

Time to start feeding based on Silverman Anderson score less than 4

Timepoint

Time to start feeding in day

Method of measurement

Calendar

5

Description

Stabilization of respiratory rate and heart rate

Timepoint

Calculate the stabilization time of respiratory rate and heart rate

Method of measurement

Hour

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 0.1 mL of salbutamol (Ventolin, salbutamol sulfate 5 mg/mL) is nebulized in 3 mL of 0.9% normal saline. The standard dose of salbutamol is 0.15 mg/kg/dose. It will be nebulized every day with a jet-type nebulizer with a continuous oxygen flow of 5 liters per minute during a 10-minute period and every 6 hours for a day

Category

Treatment - Drugs

2

Description

Control group: In the control group, they will receive 2 mL of 0.9% saline as a nebulizer.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Sina Hospital of Sari

Full name of responsible person

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Maedeh Gouran
Position
Resident of Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document

Contact Dr. Roya Farhadi

When the data will become available and for how long

Informations will send within few days after the email.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Contact Dr. Roya Farhadi

From where data/document is obtainable

Email

What processes are involved for a request to access data/document

Informations will send within few days after the email.

Comments