

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of nebulized salbutamol on Transient Tachypnea of Neonates (TTN) treatment in Neonatal Intensive Care Unit (NICU) of Rajaei hospital of Tonekabon.

Protocol summary

Study aim

The effects of nebulized salbutamol on TTN treatment in NICU of Rajaei hospital of Tonekabon.

Design

This double blinded randomized clinical trial is aimed to assess the efficacy of nebulized salbutamol in neonates with transient tachypnea. 88 neonates are evaluated in this study. For block randomization www.sealedenvelope.com site is used.

Settings and conduct

This study is conducted in NICU department of Shahid Rajjaei Hospital of Tonekabon. Neonates with the diagnosis of TTN are randomly assigned to either groups and treated accordingly. Investigators, caregivers and data analysers are blinded to the treatments. Treatments are coded by a pharmacy technician and each patient is assigned to a unique code.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of Transient Tachypnea of Neonates
Exclusion criteria: 1- Diagnosis of Respiratory Distress Syndrome
2-Sign of End-organ damage
3- Diagnosis of Sepsis

Intervention groups

In this study inhaled nebulized solution of salbutamol sulfate 0.1mL (5mg/mL) in 2 cc 0.9% saline is used in intervention group. In placebo group 2 cc 0.9% saline is used. All treatments are delivered in single dose through nebulizer.

Main outcome variables

TTN score 20 minutes and 6 hours after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170201032346N4**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **retrospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

Registration date

2020-11-28, 1399/09/08

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 91155226108

Email address

firoozihosein@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

The effects of nebulized salbutamol on Transient Tachypnea of Neonates (TTN) treatment in Neonatal Intensive Care Unit (NICU) of Rajaei hospital of Tonekabon.

Public title

The effects of nebulized salbutamol on transient tachypnea of neonates treatment.	
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Diagnosis of TTN before 6 hour of birth according to Rawling and Smith criteria. Exclusion criteria: Diagnosis of respiratory distress syndrome Presence of end-organ dysfunction Sepsis Diagnosis
Age	To 3 days old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 88 Actual sample size reached: 80
Randomization (investigator's opinion)	Randomized
Randomization description	participant are randomized with Distance randomization method. two groups of 44 patients are assigned to treatment or placebo group. each patient is assigned to a unique code provided by Distance randomization service from www.sealedenvelope.com.
Blinding (investigator's opinion)	Double blinded
Blinding description	Placebo are provided by the company producing the product. in terms of appearance drug and placebo are identical. Caregivers prescribe the drug. The research technician is assigned to lead two arms of study based on patient's assigned group. Caregivers, investigators and data analyser are blinded to the study groups.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Mazandaran University of Medical

Sciences
Street address
Mazandaran University of Medical Sciences, Vice Chancellor of Research, Moalem st, Moalem sq, Sari, Mazandaran, Iran.
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Postal code
4816715793
Approval date
2020-11-25, 1399/09/05
Ethics committee reference number
IR.MAZUMS.REC.95.2588

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

TTN score

Timepoint

20 minutes and 6 hours after treatment

Method of measurement

According to clinical severity criteria of transient tachypnea of neonates, disease is scored from 0 to 13. Higher score indicate more severe disease. The criteria includes: Expiratory grunting: None=0, Intermittent=1, Continuous=2. Supraclavicular Retraction: None=0, Mild=1, Moderate=2, Severe=3. Subcostal Retraction: None=0, Mild=1, Moderate=2, Severe=3. Cyanosis: None=0, Acral=1, Central=2. Nasal Flaring: None=0, Mild=1, Moderate=2, Severe=3.

2

Description

Heart rate

Timepoint

20 minutes and 6 hours after treatment

Method of measurement

Cardiac Monitoring. Beats per minutes

3

Description

Respiratory rate

Timepoint

20 minutes and 6 hours after treatment

Method of measurement

Cardiac Monitoring. cycle per minutes

4

Description

O2 Saturation

Timepoint

20 minutes and 6 hours after treatment

Method of measurement

Pulseoximeter, Percentage.

5

Description

Body temperature

Timepoint

20 minutes and 6 hours after treatment

Method of measurement

Thermometer. degree of Celsius.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inhalational 15mg/kg salbutamol (Ventolin Respiratory Solution, salbutamol sulfate 5 mg/mL) in 2 mL of 0.9 saline in a single dose is administered by nebulizer.

Category

Treatment - Drugs

2

Description

Control group: 2 cc of 0.9% saline is used in a single dose by nebulizer.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaei hospital of Tonekabon

Full name of responsible person

Firouzi Hossein

Street address

Rajaei hospital, Emam Khomeini Ave., Tonekabon Mazandaran. Mazandaran.

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firoozihosein@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ramsar Campus, Mazandaran University of Medical Sciences

Full name of responsible person

Davood Farzin

Street address

No.20 ,Taleghani Ave., Ramsar.

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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

Ramsar Campus, 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

Ramsar Campus, Mazandaran University of Medical Sciences

Full name of responsible person

Firouzi Hossein

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

Yes - There is 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

all collected deidentified data for primary and secondary outcome measures are going to be shared

When the data will become available and for how long

after publishing the study, data are going to be available

To whom data/document is available

data are going to be available to all researchers and clinician irrespective to their employment sector

Under which criteria data/document could be used

permission are granted upon request for secondary and meta-analysis

From where data/document is obtainable

requests are gathered through principle researcher's e-mail address

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

upon verification of request and reason data are given in three month.

Comments