

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of inhaled salbutamol With placebo (water for inj.) as an add-therapies on the duration of stay of newborns and the Recovery process of tachypnea and o2 dependence in transient tachypnea of Newborns in NICU in Qom hospitals: a clinical trial study

Protocol summary

Study aim

The effect of inhaled salbutamol on the duration of stay of newborns, and the recovery of tachypnea and O2 dependence in newborns with transient tachypnea

Design

Randomized double-blind Clinical trials with a control group, with parallel groups.

Settings and conduct

60 newborns(diagnosed with TTN in the NICU department of hospitals in Qom province) with random allocation block method will be assigned into intervention and control groups. The intervention group received routine treatment with salbutamol and the control group received routine treatment with placebo (distilled water). In each group, the infants are placed in a nebulizer for 4 doses at 12-hour intervals (10 minutes for each time) within 48 hours by NICU physicians and nurses, and examining the consequences by the physician at intervals of 30 minutes, one hour and 4 hours after The treatment will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy term infants with mild to moderate respiratory distress. Exclusion criteria: multiple anomalies; severe infection; metabolic disease.

Intervention groups

Control group receiving placebo; intervention group receiving salbutamol inhaler

Main outcome variables

Clinical TTN score; respiratory rate; heart rate; NICU duration of stay; blood oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190503043457N1**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

Registration date

2019-05-28, 1398/03/07

Registrant information

Name

Alireza saadati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3665 1801

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of inhaled salbutamol With placebo (water for inj.) as an add-therapies on the duration of stay of

newborns and the Recovery process of tachypnea and o2 dependence in transient tachypnea of Newborns in NICU in Qom hospitals: a clinical trial study

Public title

Comparison of inhaled salbutamol with placebo (water for inj.) on recovery process of newborns' transient tachypnea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A healthy term newborn with mild to moderate respiratory distress

Exclusion criteria:

Multiple anomalies Severe infection Metabolic disease

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A random block allocation method will be used. In this way, 11 blocks of four will be considered. Then, using the random number table for each block, one of the following conditions will be considered: AABB, ABAB, ABBA, BBAA, BABA, BAAB.

Blinding (investigator's opinion)

Double blinded

Blinding description

Doctors and nurses and participants do not know who is in which group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qom University of Medical Sciences

Street address

No 83, alley 4, safashahr St.

City

Qom

Province

Ghoum

Postal code

0000000000

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.MUQ.REC.1397.205

Health conditions studied**1****Description of health condition studied**

Transient tachypnea of Newborns

ICD-10 code

P22.1

ICD-10 code description

Transient tachypnoea of newborn

Primary outcomes**1****Description**

Number of breaths

Timepoint

30 minutes, one and four hours after treat

Method of measurement

By physician based on the number of breaths per minute

2**Description**

Percent saturation of oxygen

Timepoint

30 minutes, one and four hours after treat

Method of measurement

By pulse oximetry

3**Description**

Heart rate

Timepoint

30 minutes, one and four hours after treat

Method of measurement

By pulse oximetry

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving Salbutamol at a dose of 0.15 mg/kg body weight in 4 cc normal saline by nebulizer for 10 minutes

Category

Treatment - Drugs

2

Description

Control group: Receiving four cc distilled water by nebulizer for 10 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Masoumeh Children Hospital

Full name of responsible person

Alireza saadati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Qom university of medical sciences

Full name of responsible person

Hossein saghafi

Street address

Ghadir Blvd, After Park Boostan Ghadir, in front of Yadegar Imam Stadium, Complex Campus, Faculty of Medicine

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dr.hosseinsaghafi@gmail.com

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 and technology, Qom 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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad mahmoudi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Alireza saadati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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