

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

the study of Inhaled Salbutamol Influence on the Outcome of Transient Tachypnea of the Newborn in the imam khomeini hospital

Protocol summary

Summary

Aim of study: The aim of this study was to evaluate the effect of oral administration of salbutamol on the clinical course of TTN. Design of study: In this single center clinical trial study, 148 patients with TTN were randomly divided into two groups. Inclusion criteria included: tachypnea (RR > 60) during the first 6 hours of birth, continuity of tachypnea for at least 12 hours and the CXR view, and exclusion criteria included neonates with congenital anomalies, proven systemic infection (positive blood culture), meconium aspiration, respiratory distress syndrome (based on the graph), intrauterine growth retardation, history of fetal distress, pneumonitis, congenital heart disease, DIC, multi organ failure, hypocalcemia, hypoglycemia and polycythemia. Subotomol and normal saline (placebo) were administered in the intervention and control groups, respectively. Medication of newborns start at 6 birthday (up to 72 hours after starting treatment). Respiratory rate, heart rate, FIO₂, O₂ saturation were measured at 30 minutes, 1 and 4 hours after each intervention, To evaluate the response to salbutamol anesthetic. The results of the study were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062129336N3**

Registration date: **2017-07-22, 1396/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-22, 1396/04/31

Registrant information

Name

Arash Malakian

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor research of Ahvaz Jundishapur University of Medical sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the study of Inhaled Salbutamol Influence on the Outcome of Transient Tachypnea of the Newborn in the imam khomeini hospital

Public title

Influence of Inhaled Salbutamol on the Outcome of Transient Tachypnea of the Newborn

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Rawlings and Smith's criteria include:

1) Tachypnea (RR > 60) during the first 6 hours of birth 2)

Continuity of tachypnea for at least 12 hours 3) The CXR view consists of at least one of the following: elevation of the central vessels of the lung, increasing the thickness of the lobes between the lobes due to fluid accumulation, congestion of the navel of both lungs, airy lung, ie flattening of the diaphragm or enlargement of the anterior posterior chest or both Exclusion criteria: 1) Neonates with congenital anomalies 2) Proven systemic infection (positive blood culture) 3) Meconium aspiration 4) Respiratory distress syndrome (based on the graph) 5) Intrauterine growth retardation 6) history of fetal distress, pneumonitis, congenital heart disease, DIC, multi organ failure, hypocalcemia, hypoglycemia and polycythemia

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **148**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishaour University of Medical Sciences

Street address

Khuzestan, Ahvaz, Golestan, Ahvaz Jundishaour
University of Medical Sciences

City

Ahvaz

Postal code

Approval date

2015-02-21, 1393/12/02

Ethics committee reference number

ajums.REC.1393.390

Health conditions studied

1

Description of health condition studied

Transient tachypnoea of newborn

ICD-10 code

P22.1

ICD-10 code description

Transient tachypnoea of newborn

Primary outcomes

1

Description

Breathing rate

Timepoint

30 min, 1 and 4 h after Intervention

Method of measurement

Number of breaths per minute

2

Description

heart beat

Timepoint

30 min, 1 and 4 h after Intervention

Method of measurement

heart beat per minute

3

Description

Fraction of inspired oxygen

Timepoint

30 min, 1 and 4 h after Intervention

Method of measurement

FIO2 %

4

Description

o2 saturation

Timepoint

30 min, 1 and 4 h after Intervention

Method of measurement

Pulse oximetry

Secondary outcomes

1

Description

glucose

Timepoint

12 h after intervention

Method of measurement

blood test

2

Description

potassium

Timepoint

12 h after intervention
Method of measurement
blood test

3

Description
Arterial blood gas
Timepoint
12 h after intervention
Method of measurement
blood test

Intervention groups

1

Description
Intervention group: Salbutamol was administered in the intervention group. The solution was administered as an inhaler and through a nebulizer jet with an oxygen flow rate of 6-5 liters per minute. The medication was taken at 20 minutes each intervention. If the respiratory distress continued and oxygen was needed, the salbutamol was prescribed every 6 hours, for 72 hours after starting treatment. The dose of Salbutamol was 0.15 mg / kg body weight. If patient needed ventilator during treatment, intervention was stopped.
Category
Treatment - Drugs

2

Description
Control group: Normal saline (placebo) was administered in the control group. The solution was administered as an inhaler and through a nebulizer jet with an oxygen flow rate of 6-5 liters per minute. The intervention was taken at 20 minutes each intervention. If the respiratory distress continued and oxygen was needed, the normal saline was prescribed every 6 hours, for 72 hours after starting treatment. If patient needed ventilator during treatment, intervention was stopped.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Dr Arash Malakian
Street address
Ahvaz Jundishapur University of Medical Sciences
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor research of Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr Behzad Sharif Makhmalzadeh
Street address
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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 research of Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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

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Full name of responsible person

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Position

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Other areas of specialty/work