Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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

Ahvaz

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

Full name of responsible person

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Position

Faculty member

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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