Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigation the effectiveness of inhaled salbutamol in the treatment of transient tachypnea of the newborn

Protocol summary

Summary

This study will be done with the aim of investigation the effectiveness of inhaled salbutamol in the treatment of transient tachypnea of the newborn. This study is one blinded clinical trial. The study population will be included infants hospitalized in intensive care unit of Imam Reza Hospital. 80 newborns will be selected in available method and will be randomly assigned into two intervention and control groups. The intervention group will receive an inhaled salbutamol with dose of 0.15mg that is equal to 0.15ml per kilogram of body weight by nebulizer for 20 minutes. The control group will receive normal saline solution 0.9% equal to 0.15 ml per kg body weight by nebulizer for 20 minutes. Before and after treatment, at intervals of 30 minutes, one and four hours after the start of treatment, the number of respiration, heart rate, oxygen saturation, oxygen consumption, respiratory distress score, and hospitalization time is recorded in the checklist and two groups are compared Inclusion criteria: Neonates with term of gestational age; Near term or after term; Having clinical symptoms and biographies in favor of TTN diagnosis; Having at least one of the radiographic TTN criteria (including hyperinflation, the presence of fluid in the transverse Fisher, etc). Exclusion criteria: Meconium aspiration history; Respiratory distress syndrome; Congenital pneumonia; Polycysthemia; Hypoglycemia; Prolonged early sepsis; Cardiovascular disease; Tachycardia greater than 180 beats per minute; Cardiac arrhythmia; Congenital anomaly

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081414333N80**
Registration date: **2017-08-29, 1396/06/07**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-08-29, 1396/06/07

Registrant information

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Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness of inhaled salbutamol in the treatment of transient tachypnea of the newborn

Public title

Investigation the effectiveness and non effectiveness of inhaled salbutamol in the treatment of respiratory diseases

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Neonates with term of gestational age; Near term or after term; Having clinical symptoms and biographies in favor of TTN diagnosis; Having at least one of the radiographic TTN criteria (including hyperinflation, the presence of fluid in the transverse Fisher, etc). Exclusion criteria: Meconium aspiration history; Respiratory distress syndrome; Congenital pneumonia; Polycysthemia; Hypoglycemia; Prolonged early sepsis; Cardiovascular disease; Tachycardia greater than 180 beats per minute; Cardiac arrhythmia; Congenital anomaly
Age
From **1 day** old to **2 days** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd
City
Kermanshah
Postal code
Approval date
2017-05-17, 1396/02/27
Ethics committee reference number
kums.rec.1396.80

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
Number of breaths
Timepoint
Before starting treatment and after treatment at intervals: 30 minutes, one and four hours after the start
Method of measurement
By physician based on the number of breaths per minute

2

Description
Percent saturation of oxygen
Timepoint
Before starting treatment and after treatment at intervals: 30 minutes, one and four hours after the start
Method of measurement
By pulse oximetry

3

Description
Heart rate
Timepoint
Before starting treatment and after treatment at intervals: 30 minutes, one and four hours after the start
Method of measurement
By pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive an inhaled salbutamol with dose of 0.15mg that is equal to 0.15ml per kilogram of body weight by nebulizer for 20 minutes.
Category
Treatment - Drugs

2

Description
The control group will receive normal saline solution

0.9% equal to 0.15 ml per kg body weight by nebulizer for 20 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Shohreh Dabiri

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd

City

Kermanshah

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, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Shohreh Dabiri

Position

Resident of children

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Homa Babaei

Position

Professor of Infants

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Shohreh Dabiri

Position

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Other areas of specialty/work

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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