Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of inhaler salbutamol versus placebo on treatment of neonatal transient tachypnea: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of inhaler salbutamol versus placebo on treatment of neonatal transient tachypnea. Design: A double blind randomized clinical trial. Setting and conduct: The eligible neonates with transient tachypnea who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 34 to 47 weeks; neonatal transient tachypnea. Exclusion criteria: Pneumothorax; maternal addiction; respiratory distress syndrome; meconium aspiration; pneumonia; sepsis; congenital heart disease; pulmonary hypertension. Intervention group: 0.1 ml/kg salbutamol and 2 ml normal saline 0.9% plus 5 to 6 l/min oxygen for 20 min will be nebulized. Control group: 2 ml normal saline 0.9% plus 5 to 6 l/min oxygen for 20 min will be nebulized. Primary outcome: (a) number of breathing before and 0.5, 1 and 4 hours after treatment by physical examination; (b) TTN clinical score before and 0.5, 1 and 4 hours after treatment by physical examination; (c) arterial oxygen saturation before and 4 hours after treatment by checking arterial blood sample. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201711139014N201**
Registration date: **2017-11-15, 1396/08/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-15, 1396/08/24

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of inhaler salbutamol versus placebo on treatment of neonatal transient tachypnea: a double blind randomized clinical trial

Public title

Effect of inhaler salbutamol versus placebo on treatment of neonatal transient tachypnea

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age of 34 to 47 weeks; neonatal transient tachypnea. Exclusion criteria: Pneumothorax; maternal addiction; respiratory distress syndrome; meconium aspiration; pneumonia; sepsis; congenital heart disease; pulmonary hypertension.
Age
From **8 months** old to **11 months** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
Approval date
2017-11-04, 1396/08/13
Ethics committee reference number
IR.UMSHA.REC.1396.531

Health conditions studied

1

Description of health condition studied
Neonatal transient tachypnea
ICD-10 code
P22.1
ICD-10 code description
Transient tachypnoea of newborn

Primary outcomes

1

Description
Number of breathing
Timepoint
Before and 0.5, 1 and 4 hours after treatment
Method of measurement
By physical examination

2

Description
TTN clinical score
Timepoint
Before and 0.5, 1 and 4 hours after treatment
Method of measurement
By physical examination

3

Description
Arterial oxygen saturation
Timepoint
Before and 4 hours after treatment
Method of measurement
By checking arterial blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 0.1 ml/kg salbutamol and 2 ml normal saline 0.9% plus 5 to 6 l/min oxygen for 20 min will be nebulized.
Category
Treatment - Drugs

2

Description
Control group: 2 ml normal saline 0.9% plus 5 to 6 l/min oxygen for 20 min will be nebulized.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Nishtman Sadeghi
Street address
Fatemieh Hospital, Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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 for Research and Technology, Hamadan 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
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Person responsible for updating data

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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