

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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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.

City

Hamadan

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
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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**

Fatemieh Hospital

Full name of responsible person

Dr Nishtman Sadeghi

Position

Pediatrician

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Person responsible for scientific inquiries

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Fatemieh Hospital

Full name of responsible person

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Position

Neonatologist

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Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

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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