

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 Fatemeh 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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  
Fahmideh Ave

**City**

Hamadan

**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

**Other areas of specialty/work**

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3828 3939

**Fax**

**Email**

nishti\_sadeghi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Fatemieh Hospital

**Full name of responsible person**

Dr Behnaz Basiri

**Position**

Neonatologist

**Other areas of specialty/work**

**Street address**

Fatemieh Hospital, Pasdaran Ave.

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3828 3939

**Fax**

**Email**

b.basiri@umsha.ac.ir

**Web page address**

## 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

**Other areas of specialty/work**

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Postal code**

**Phone**

+98 81 3838 0090

**Fax**

**Email**

poorolajal@umsha.ac.ir

**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*