

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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; Polycythemia; 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

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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; Polycythemia; 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**

**Street address**

Emam Reza Hospital, Parastar Boulevard

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+98 83 3427 6300

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**Email**

Dr.dabiri@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Homa Babaei

**Position**

Professor of Infants

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Dr. Shohreh Dabiri

**Position**

Resident of children

**Other areas of specialty/work**

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**Postal code**

**Phone**

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**Fax**

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Dr.dabiri@yahoo.com

**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*