

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of inhaled salbutamol With placebo (water for inj.) as an add-therapies on the duration of stay of newborns and the Recovery process of tachypnea and o2 dependence in transient tachypnea of Newborns in NICU in Qom hospitals: a clinical trial study

#### Protocol summary

##### Study aim

The effect of inhaled salbutamol on the duration of stay of newborns, and the recovery of tachypnea and O2 dependence in newborns with transient tachypnea

##### Design

Randomized double-blind Clinical trials with a control group, with parallel groups.

##### Settings and conduct

60 newborns(diagnosed with TTN in the NICU department of hospitals in Qom province) with random allocation block method will be assigned into intervention and control groups. The intervention group received routine treatment with salbutamol and the control group received routine treatment with placebo (distilled water). In each group, the infants are placed in a nebulizer for 4 doses at 12-hour intervals (10 minutes for each time) within 48 hours by NICU physicians and nurses, and examining the consequences by the physician at intervals of 30 minutes, one hour and 4 hours after The treatment will be done.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy term infants with mild to moderate respiratory distress. Exclusion criteria: multiple anomalies; severe infection; metabolic disease.

##### Intervention groups

Control group receiving placebo; intervention group receiving salbutamol inhaler

##### Main outcome variables

Clinical TTN score; respiratory rate; heart rate; NICU duration of stay; blood oxygen saturation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190503043457N1**

Registration date: **2019-05-28, 1398/03/07**

Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**

Update count: **0**

##### Registration date

2019-05-28, 1398/03/07

##### Registrant information

###### Name

Alireza saadati

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3665 1801

###### Email address

a.rsadati@muq.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of inhaled salbutamol With placebo (water for inj.) as an add-therapies on the duration of stay of

newborns and the Recovery process of tachypnea and o2 dependence in transient tachypnea of Newborns in NICU in Qom hospitals: a clinical trial study

#### Public title

Comparison of inhaled salbutamol with placebo (water for inj.) on recovery process of newborns' transient tachypnea

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

A healthy term newborn with mild to moderate respiratory distress

##### Exclusion criteria:

Multiple anomalies Severe infection Metabolic disease

#### Age

From **1 day** old to **7 days** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

A random block allocation method will be used. In this way, 11 blocks of four will be considered. Then, using the random number table for each block, one of the following conditions will be considered: AABB, ABAB, ABBA, BBAA, BABA, BAAB.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Doctors and nurses and participants do not know who is in which group.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

###### Street address

No 83, alley 4, safashahr St.

###### City

Qom

###### Province

Ghoush

#### Postal code

0000000000

#### Approval date

2019-03-05, 1397/12/14

#### Ethics committee reference number

IR.MUQ.REC.1397.205

### Health conditions studied

#### 1

##### Description of health condition studied

Transient tachypnea of Newborns

##### ICD-10 code

P22.1

##### ICD-10 code description

Transient tachypnoea of newborn

### Primary outcomes

#### 1

##### Description

Number of breaths

##### Timepoint

30 minutes, one and four hours after treat

##### Method of measurement

By physician based on the number of breaths per minute

#### 2

##### Description

Percent saturation of oxygen

##### Timepoint

30 minutes, one and four hours after treat

##### Method of measurement

By pulse oximetry

#### 3

##### Description

Heart rate

##### Timepoint

30 minutes, one and four hours after treat

##### Method of measurement

By pulse oximetry

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Receiving Salbutamol at a dose of 0.15 mg/kg body weight in 4 cc normal saline by nebulizer for 10 minutes

##### Category

Treatment - Drugs

## 2

### Description

Control group: Receiving four cc distilled water by nebulizer for 10 minutes

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Masoumeh Children Hospital

**Full name of responsible person**

Alireza saadati

**Street address**

Imam khomeini St

**City**

Qom

**Province**

Ghoum

**Postal code**

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**Phone**

+98 25 3665 1801

**Email**

a\_saadati\_md@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research and technology, Qom university of medical sciences

**Full name of responsible person**

Hossein saghafi

**Street address**

Ghadir Blvd, After Park Boostan Ghadir, in front of Yadegar Imam Stadium, Complex Campus, Faculty of Medicine

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**Province**

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3736175513

**Phone**

+98 25 3197 1121

**Email**

dr.hosseinsaghafi@gmail.com

**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, Qom university of medical sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Mohammad mahmoudi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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u.hedayati@gmil.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ghoum University of Medical Sciences

**Full name of responsible person**

Alireza saadati

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

neonatology

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**Person responsible for updating data****Contact****Name of organization / entity**

Ghoum University of Medical Sciences

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**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

neonatology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available