

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation of efficacy of combination of nebulized salbutamol with high concentration of saline (normal saline 0/9%, hypertonic saline 3%) in bronchiolitis

#### Protocol summary

##### Summary

Evaluation of efficacy of combination of nebulized salbutamol with different concentration of saline (normal saline 0/9%, hypertonic saline 3%) in infant with bronchiolitis whom admitted in Ali Ebne Ab iTaleb hospital of Zahedan, Iran. Design: randomized, double blind, without control with placebo, unicentral, stage 3 of clinical trial on infant with bronchiolitis whom admitted in hospital (age 4 weeks up to 24 months) and require oxygen therapy. Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheeze and crackle in auscultation; CBSS 4-8 in admit. Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheeze; sever neurological disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of premature (gestational age less than 34 weeks); birth weight less than 2500 gr; saturation of oxygen less than 85% in room; CBSS less than 4 or more than 8; unstable hemodynamic (heart rate more than 200 per minute, blood pressure 2 standard deviation more or less than normal range for age and sex, respiratory rate more than 70 per minute). Sample size: 180; infants who have inclusion criteria and their respiratory rate is between 30-60 (moderate group) with method of random number table divided in 3 groups, each group has 60 person. group 1 receive 5 ml normal saline 0/9 % and 0/15 mg/kg nebulized salbutamol, group 2 receive 5 ml hypertonic saline 3% and 0/15 mg/kg nebulized salbutamol, group 3 receive 10 ml normal saline 0/9 % and 0/15 mg/kg nebulized saline, then clinical features, oxygen saturation, respiratory rate, heart rate, intercostal retraction, dyspnea and wheezing evaluated pretreatment and each 30 minutes after treatment up to 3 times.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016022826809N1**  
Registration date: **2016-04-23, 1395/02/04**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-23, 1395/02/04

##### Registrant information

##### Name

Fariba Goodarzi

##### Name of organization / entity

Zahedan Medical University of Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5580

##### Email address

f.goodarzi@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Zahedan University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-02-04, 1393/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of efficacy of combination of nebulized salbutamol with high concentration of saline (normal saline 0/9%, hypertonic saline 3%) in bronchiolitis

### Public title

Comparing Therapeutic effects of combination of high volume normal saline and salbutamol nebulizer with combination of hypertonic saline 3% and salbutamol nebulizer in bronchiolitis treatment

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheeze and crackle in auscultation; CBSS 4-8 in admit.  
Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheeze; sever neurological disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of premature (gestational age less than 34 weeks); birth weight less than 2500 gr; saturation of oxygen less than 85% in room; CBSS less than 4 or more than 8; unstable hemodynamic (heart rate more than 200 per minute, blood pressure 2 standard deviation more or less than normal range for age and sex, respiratory rate more than 70 per minute).

### Age

From **1 month** old to **2 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **180**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan Medical University of

Science

#### Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

#### City

Zahedan

#### Postal code

#### Approval date

2014-06-28, 1393/04/07

#### Ethics committee reference number

IR.zaums.res.1393.6792

## Health conditions studied

### 1

#### Description of health condition studied

Bronchiolitis

#### ICD-10 code

J20, J21.J

#### ICD-10 code description

Other acute lower respiratory infections

## Primary outcomes

### 1

#### Description

Respiratory rate

#### Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

#### Method of measurement

Counting respiratory rate in 1 minute

### 2

#### Description

O2 saturation

#### Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

#### Method of measurement

Pulse oximetry

### 3

#### Description

Heart rate

#### Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

#### Method of measurement

Counting heart rate in 1 minute

### 4

#### Description

Intercostal retraction

#### Timepoint

Pretreatment and each 30 minute up to 3 times after the

begining of treatment  
**Method of measurement**  
Physical exam and score of CBSS (0,1,2,3)

## 5

**Description**  
Dyspnea  
**Timepoint**  
Pretreatment and each 30 minute up to 3 times after the begining of treatment  
**Method of measurement**  
Physical exam and score of CBSS (0,1,2,3)

## 6

**Description**  
Wheezing  
**Timepoint**  
Pretreatment and each 30 minute up to 3 times after the begining of treatment  
**Method of measurement**  
Physical exam and score of CBSS (0,1,2,3)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**  
First group: receive 5 ml hypertonic saline 3% and 0.15 mg/kg nebulized salbutamol.  
**Category**  
Treatment - Drugs

### 2

**Description**  
Second group: receive 5 ml normal saline 0.9% and 0.15 mg/kg nebulized salbutamol.  
**Category**  
Treatment - Drugs

### 3

**Description**  
Third group: receive 10 ml normal saline 0.9% and 0.15 mg/kg nebulized salbutamol.  
**Category**  
Treatment - Drugs

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Ali-ebn Abi -Taleb Hospital, Zahedan  
**Full name of responsible person**  
**Street address**

**City**  
Zahedan

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Vice chancellor for research,Zahedan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Taheri  
**Street address**  
Vice chancellor for research, Zahedan University of Medical Sciences, Hesabi Square, Zahedan  
**City**  
Zahedan  
**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,Zahedan 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**  
Zahedan Medical University  
**Full name of responsible person**  
Fariba Goodarzi  
**Position**  
Pediatric Residence  
**Other areas of specialty/work**  
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Ali-ebn Abi Taleb Hospital,Salamat Blvd, Dr.Hesabi Sq.,Daneshgah Ave., Zahedan  
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## Person responsible for scientific inquiries

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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*

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fariba Goodarzi