

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### A randomized clinical trial to compare efficacy of nebulized hypertonic saline and normal saline in Length of hospital stay and severity score in children with acute bronchiolitis

#### Protocol summary

##### Study aim

Comparison the efficacy of nebulized hypertonic(3%, 5% and 7% ) saline with normal saline in infants hospitalized with acute bronchiolitis

##### Design

120 children with moderate to severe bronchiolitis randomly assigned into four groups to receive nebulized normal saline(group A), saline 3%(group B), saline 5% (group C) and saline 7% (group D).

##### Settings and conduct

The study was done in emergency department of children hospitals in Isfahan. For each patient a vial labeled with a code was selected by chance and no one( parents of the patient, evaluators, analyzer) knew about content of the vial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: any infant from 1-24 months old with acute onset of respiratory distress and presence of wheezing on examination Exclusion criteria: evidence of atopy; history of prematurity (birth before 34 weeks or equal to); history of wheezing; history of previous bronchodilators or glucocorticoids use; loss of consciousness; history of chronic heart, pulmonary, neurologic, oncologic and immunologic disease.severe respiratory distress; respiratory failure requiring intubation or ICU admission Early discharge (less than 24 hours from admission) , need for intubation or ICU care in the course of disease

##### Intervention groups

infants with bronchiolitis treated with nebulized normal saline infants with bronchiolitis treated with nebulized 3% saline infants with bronchiolitis treated with nebulized 5% saline infants with bronchiolitis treated with nebulized 7% saline

##### Main outcome variables

Length of hospital stay (as primary outcome) and the use of oxygen, temperature, oxygen saturation (SPO2), pulse

rate (PR), respiratory rate (RR) and bronchiolitis severity score (BRAS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141201020175N3**

Registration date: **2018-03-02, 1396/12/11**

Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**

Update count: **0**

##### Registration date

2018-03-02, 1396/12/11

##### Registrant information

##### Name

Mohsen Reisi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 3678

##### Email address

mohsenreisi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2015-06-05, 1394/03/15

**Actual recruitment start date**

2015-11-22, 1394/09/01

**Actual recruitment end date**

2016-06-04, 1395/03/15

**Trial completion date**

empty

**Scientific title**

A randomized clinical trial to compare efficacy of nebulized hypertonic saline and normal saline in Length of hospital stay and severity score in children with acute bronchiolitis

**Public title**

Efficacy of hypertonic saline in acute bronchiolitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

acute onset of respiratory distress prodromal respiratory symptoms presence of wheezing on examination severity score (BRAS) equal five or more infants 1-24 months old

**Exclusion criteria:**

history of atopy history of prematurity (birth before 34 weeks or equal to) history of wheezing history of previous use of bronchodilators or glucocorticoids use loss of consciousness history of chronic heart, pulmonary, neurologic, oncologic and immunologic disease

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **120**

Actual sample size reached: **127**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random Allocation was done by using a computer-generated list of random numbers to identify 1 of 4 codes identifying 1 of 4 different 100-mL bags of sterilely prepared blinded study solution containing 7%, 5%, 3%, or 0.9% saline.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

All the vials containing normal saline and different degree of hypertonic saline were labeled by a number code and for each patient one code would be selected by chance for treatment. Non of the parents of the patients (patients are infants), health care providers, physicians evaluating BRAS score before and after intervention,

data collectors and outcome assessors knows the density of the each vial.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan university of medical science, Hezarjarib street, Azadi square

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2015-11-22, 1394/09/01

**Ethics committee reference number**

IR.MUI.REC.1394.3.242

**Health conditions studied****1****Description of health condition studied**

Acute bronchiolitis

**ICD-10 code**

J21

**ICD-10 code description**

with bronchospasm

**Primary outcomes****1****Description**

Bronchiolitis respiratory assessment score (BRAS)

**Timepoint**

Before intervention and then every 4 hours

**Method of measurement**

Bronchiolitis respiratory assessment score (BRAS)

**2****Description**

length of hospital stay

**Timepoint**

At discharge

## Method of measurement

Patient record

## Secondary outcomes

### 1

#### Description

Respiratory rate

#### Timepoint

Before intervention and then every 4 hour

#### Method of measurement

observation

### 2

#### Description

Temperature

#### Timepoint

Before intervention and then every 4 hour

#### Method of measurement

Thermometer

### 3

#### Description

Heart rate

#### Timepoint

Before intervention and then every 4 hour

#### Method of measurement

determining pulse rate by use a chronometer

### 4

#### Description

O2 saturation

#### Timepoint

Before intervention and then every 4 hour

#### Method of measurement

pulse oximeter

## Intervention groups

### 1

#### Description

Nebulize of 4 mL normal saline(0.9%) with 1.5 mL of epinephrine (1 /1000) through the mouth mask with 4 L / min oxygen; every 4 hours

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Nebulize of 4 mL hypertonic saline(3%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: Nebulize of 4 mL hypertonic saline(5%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours

#### Category

Treatment - Drugs

### 4

#### Description

Intervention group: Nebulize of 4 mL hypertonic saline(7%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein hospital

##### Full name of responsible person

Dr. Mohsen Reisi

##### Street address

Imam Hossein hospital, Imam Khomeini street, Isfahan

##### City

Isfahan

##### Province

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##### Postal code

411381515737

##### Phone

+98 31 3386 6266

##### Email

mohsenreisi@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor of research, Isfahan University of Medical Sciences

##### Full name of responsible person

Dr. Mohsen Reisi

##### Street address

Vice-chancellor of research, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan

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**Email**

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https://mui.ac.ir/

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor of research, Isfahan 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**

Vice-chancellor of research of Isfahan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Reisi

**Position**

Pediatric pulmonologist, Assistant professor of Isfahan University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Child Growth and Development Research Center,

Pediatric Pulmonology Department, Research Institute  
0

**Full name of responsible person**

Dr. Mohsen Reisi

**Position**

Pediatric pulmonologist, Assistant professor of Isfahan University of Medical Sciences

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Isfahan University of Medical Science

**Full name of responsible person**

Narges Afkande

**Position**

Pediatric specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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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