

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effectiveness and non-effectiveness of saline 3% and salbutamol in the treatment of patients with acute bronchiolitis

#### Protocol summary

##### Summary

This study will be done with aimed to determine the effect of 3% saline solution and salbutamol in patients with acute bronchiolitis. This study is a single blind clinical trial. The study population would be consisted of children with respiratory bronchiolitis admitted to Mohammad Kermanshahy hospital in Kermanshah city that the number of 64 cases is selected and randomly are placed in two control and study groups. Before starting treatment the patient's symptoms, such as overall health, chest auscultation in terms of wheezing, respiratory rate, blood oxygen concentration and temperature are recorded. In the experimental group, 4 ml Lytrsalyh hypertonic 3% plus 15/0 mg/kg salbutamol every 8 hours is given by nurse. And for the control group just 15/0 mg / kg Salbutamol is given every 8 hours. Then in both groups, patients' symptoms such as cough, chest auscultation in terms of wheezing, respiratory rate, blood oxygen saturation, lung retraction, the temperature of patient and overall health in daily visit (every 24 hours by a specialist) are recorded. While patient discharge the number of days of hospitalization is recorded and bronchiolitis severity measured and is determined. Inclusion criteria: Children under 2 years old, children with acute bronchiolitis. Exclusion criteria: children with cystic fibrosis, bronchopulmonary dysplasia and those with heart disease, premature babies with GA $\leq$ 34; patients who had used steroids during the last 48 hours prior to admission; children with immunodeficiency

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092214333N39**

Registration date: **2015-11-03, 1394/08/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-11-03, 1394/08/12

##### 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

Kermanshah University of Medical Sciences, Vice Chancellor for Research

##### Expected recruitment start date

2015-02-04, 1393/11/15

##### Expected recruitment end date

2015-07-06, 1394/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness and non-effectiveness of saline 3% and salbutamol in the treatment of patients with acute bronchiolitis

##### Public title

The effect of 3% hypertonic saline and salbutamol in treatment of patients with acute bronchiolitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: children under 2 years old; children with acute bronchiolitis. Exclusion criteria: children with cystic fibrosis; bronchopulmonary dysplasia and those with heart disease; premature babies with GA $\leq$ 34; patients who had used steroids during the last 48 hours prior to admission; children with immunodeficiency.

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomly by throwing coins

**Secondary Ids**

empty

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

Ethics committee, Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Postal code****Approval date**

2015-02-22, 1393/12/03

**Ethics committee reference number**

16379/پ/707/7آ

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

Acute bronchiolitis

**ICD-10 code**

J21

**ICD-10 code description**

Acute bronchiolitis

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

Chest auscultation in terms of wheezing

**Timepoint**

Beginning and end of study

**Method of measurement**

By a doctor

**2****Description**

Cough

**Timepoint**

Beginning and end of study

**Method of measurement**

By doctor and counting

**3****Description**

Respiratory rate

**Timepoint**

Beginning and end of study

**Method of measurement**

By doctor and counting

**4****Description**

Blood oxygen saturation

**Timepoint**

Beginning and end of study

**Method of measurement**

By pulse oximeter

**5****Description**

Lung retraction

**Timepoint**

Beginning and end of study

**Method of measurement**

Based on physician observation

**6****Description**

The temperature of patient

**Timepoint**

Beginning and end of study

**Method of measurement**

Thermometer device

## 7

### **Description**

overall health of Patient

### **Timepoint**

Beginning and end of study

### **Method of measurement**

Based on physician observation and patient interview

## 8

### **Description**

The severity of bronchiolitis

### **Timepoint**

Beginning and end of study

### **Method of measurement**

Based on the observations and examined by a doctor

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group just 15/0 mg / kg Salbutamol will given every 8 hours

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Experimental group, 4 ml Lytrsalyng hypertonic 3% plus 15/0 mg/kg salbutamol every 8 hours will given by nurse

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mohammad Kermanshahi Hospital

##### **Full name of responsible person**

Negin Bakhtiari

##### **Street address**

Mohammad Kermanshahi Hospital

##### **City**

Kermanshah

## **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**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

#### **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**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Dr. Hamidreza Mortazavi

##### **Position**

Pediatrician

##### **Other areas of specialty/work**

##### **Street address**

Emamreza Hospital, Parastar Boulevard

##### **City**

Kermanshah

##### **Postal code**

##### **Phone**

+98 83 3427 6309

##### **Fax**

##### **Email**

dr\_mormd@yahoo.com

##### **Web page address**

## **Person responsible for updating data**

#### **Contact**

## **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*