

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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/707/7/آ

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 Lytrsalyn 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

Korosh 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