Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Lytrsalyn hypertonic 3% plus15/0 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≤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
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Iran (Islamic Republic of)
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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≤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% plus15/0 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
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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