Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of efficacy of combination of nebulized salbutamol with different concentration of saline (normal saline 0/9%, hypertonic saline 3%, hypertonic saline 5%) 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%, hypertonic saline 5%) in infant with bronchiolitis whom admitted in ali ebne abitaleb hospital of Zahedan, Iran. Design: randomized, double blind, without control with blacebo, unicentral, stage 2 of clinical trial on infant with bronchiolitis whom admitted in hospital(age 4 weeks upto 24 months) and requier oxygen therapy. Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheez and crakle in ascultation; CBSS 4-8 in admit. Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheez; sever neurologic disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of prematurity(gestational age less than 34 weeks); birth weight less than 2500 gr; sturation 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 devided 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 5 ml hypertonic saline 5 % and 0/15 mg/kg nebulized saline, then clinical features, oxygen saturation, respiratory rate, heart rate, intercostal retraction, dyspnea and wheez evaluated pretreatment and each 20 minutes after treatment upto 3 times.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050213207N1**
Registration date: **2013-08-26, 1392/06/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name
Maryam Baktash
Name of organization / entity
Zahedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2012-10-14, 1391/07/23

Expected recruitment end date

2014-01-21, 1392/11/01

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 different concentration of saline (normal saline 0/9%, hypertonic saline 3%, hypertonic saline 5%) in bronchiolitis

Public title
Treatment of bronchiolitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheez and crakle in ascultation; CBSS 4-8 in admit. Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheez; sever neurologic disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of prematurity(gestational age less than 34 weeks); birth weight less than 2500 gr; sturation 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
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
Zahedan University of Medical Scences
Street address
Zahedan University of Medical Scences
City
Zahedan
Postal code
9816743463
Approval date
2012-10-13, 1391/07/22
Ethics committee reference number
91-1164

Health conditions studied

1

Description of health condition studied
Bronchiolitis
ICD-10 code
J20-22
ICD-10 code description
Other acute lower respiratory infections

Primary outcomes

1

Description
O2 saturation
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of the treatment
Method of measurement
With pulse oximetery

2

Description
Respiratory rate
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of treatment
Method of measurement
Counting of respiratory rate in 1 minute

3

Description
Heart rate
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of teratment
Method of measurement
Counting of the heart rate in 1 minute

4

Description
Intercostal retraction
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of the treatment
Method of measurement
Physical exam and score of CBSS (0,1,2,3)

5

Description
Dyspnea
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of the treatment
Method of measurement
Physical examine and score of CBSS(0,1,2,3)

6

Description
Wheeze
Timepoint
Pretreatment and each 20 minute up to 3 times after the begining of the treatment
Method of measurement
Physical exam and score of the CBSS(0,1,2,3)

Secondary outcomes

1

Description
Duration of admission
Timepoint
From admossion up to discharge from hospital
Method of measurement
Counting of the dyes of admission

Intervention groups

1

Description
Infants who have inclusion criteria and their respiratory rate is between 30 - 60 per minute devide in 3 groups. First group receive 5 ml normal saline 0/9 % and 0/15 mg/kg nebulized salbutamol
Category
Treatment - Drugs

2

Description
Second group receive 5 ml hypertonic saline 3 % and 0/15 mg/kg nebulized salbutamol.
Category
Treatment - Drugs

3

Description
Third group receive 5 ml hypertonic saline 5% and 0/15 mg/kg nebulized salbutamol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Almomenin hospital
Full name of responsible person
Maryam Baktash
Street address
Amir Almomenin hospital, Zahedan
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice.chancellor for research of Zahedan University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Mahmoodzade
Street address
Zahedan University of Medical Sciences
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 of 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 University of Medical Sciences
Full name of responsible person
Maryam Baktash
Position
md, pediatric resident
Other areas of specialty/work
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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