

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy of combination of nebulized salbutamol with high concentration of saline (normal saline 0/9%, hypertonic saline 3%) 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%) in infant with bronchiolitis whom admitted in Ali Ebne Ab iTaleb hospital of Zahedan, Iran. Design: randomized, double blind, without control with placebo, unicentral, stage 3 of clinical trial on infant with bronchiolitis whom admitted in hospital (age 4 weeks up to 24 months) and require oxygen therapy. Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheeze and crackle in auscultation; CBSS 4-8 in admit. Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheeze; sever neurological disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of premature (gestational age less than 34 weeks); birth weight less than 2500 gr; saturation 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 divided 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 10 ml normal saline 0/9 % and 0/15 mg/kg nebulized saline, then clinical features, oxygen saturation, respiratory rate, heart rate, intercostal retraction, dyspnea and wheezing evaluated pretreatment and each 30 minutes after treatment up to 3 times.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022826809N1**

Registration date: **2016-04-23, 1395/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-23, 1395/02/04

Registrant information

Name

Fariba Goodarzi

Name of organization / entity

Zahedan Medical University of Science

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5580

Email address

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Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-02-04, 1393/11/15

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

Public title

Comparing Therapeutic effects of combination of high volume normal saline and salbutamol nebulizer with combination of hypertonic saline 3% and salbutamol nebulizer in bronchiolitis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age less than 2 year old; history of recent upper respiratory viral infection which caused wheeze and crackle in auscultation; CBSS 4-8 in admit.
Exclusion criteria: age less than 1 month or more than 2 years old; history of recurrent attack of wheeze; sever neurological disorder; consolidation in Chest x ray; immune deficiency; congenital heart disease; history of premature (gestational age less than 34 weeks); birth weight less than 2500 gr; saturation 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

From **1 month** old 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

Ethics Committee of Zahedan Medical University of

Science

Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Daneshgah Avenue, Zahedan

City

Zahedan

Postal code

Approval date

2014-06-28, 1393/04/07

Ethics committee reference number

IR.zaums.res.1393.6792

Health conditions studied

1

Description of health condition studied

Bronchiolitis

ICD-10 code

J20, J21,J

ICD-10 code description

Other acute lower respiratory infections

Primary outcomes

1

Description

Respiratory rate

Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

Method of measurement

Counting respiratory rate in 1 minute

2

Description

O2 saturation

Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

Method of measurement

Pulse oximetry

3

Description

Heart rate

Timepoint

Pretreatment and each 30 minute up to 3 times after the begining of treatment

Method of measurement

Counting heart rate in 1 minute

4

Description

Intercostal retraction

Timepoint

Pretreatment and each 30 minute up to 3 times after the

begining of treatment
Method of measurement
Physical exam and score of CBSS (0,1,2,3)

5

Description
Dyspnea
Timepoint
Pretreatment and each 30 minute up to 3 times after the begining of treatment
Method of measurement
Physical exam and score of CBSS (0,1,2,3)

6

Description
Wheezing
Timepoint
Pretreatment and each 30 minute up to 3 times after the begining of treatment
Method of measurement
Physical exam and score of CBSS (0,1,2,3)

Secondary outcomes

empty

Intervention groups

1

Description
First group: receive 5 ml hypertonic saline 3% and 0.15 mg/kg nebulized salbutamol.
Category
Treatment - Drugs

2

Description
Second group: receive 5 ml normal saline 0.9% and 0.15 mg/kg nebulized salbutamol.
Category
Treatment - Drugs

3

Description
Third group: receive 10 ml normal saline 0.9% and 0.15 mg/kg nebulized salbutamol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali-ebn Abi -Taleb Hospital, Zahedan
Full name of responsible person
Street address

City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
Street address
Vice chancellor for research, Zahedan University of Medical Sciences, Hesabi Square, Zahedan
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,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 Medical University
Full name of responsible person
Fariba Goodarzi
Position
Pediatric Residence
Other areas of specialty/work
Street address
Ali-ebn Abi Taleb Hospital,Salamat Blvd, Dr.Hesabi Sq.,Daneshgah Ave., Zahedan
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan Medical University

Full name of responsible person

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Position

Pediatric Residence

Other areas of specialty/work**Street address**

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Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fariba Goodarzi