Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Zahedan Medical University of Science
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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

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 oximetery

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

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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