Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the efficacy of Nebulized 3% hypertonic saline solution and 0.9% normal saline in2-24 m/o children with acute bronchiolitis.

Protocol summary

Summary

The purpose of the current study is to compare the effect of nebulized 3% hypertonic saline in treatment of bronchiolitis with nebulized 0.9% normal saline in 2-24 month children. In a non-randomized controlled trial during two falls and two winters from 2008-2010, the study population was all 2-24 month children with diagnosis of acute bronchiolitis referring to Ali-e-Asghar Pediatric center. Inclusion criteria were: first or second episode of respiratory distress with wheezing and clinical manifestation of viral infection e.g. temperature >= 38 degree of centigrade, respiratory rate >=100, pulse rate >= 180 or coryza. Exclusion criteria were: chronic respiratory or cardiac disease, immunodeficiency, Down syndrome, Metabolic or neurologic disorders, history of prematurity (gestational age < 34 wks), mechanical ventilation in neonatal period, family history of asthma and toxic patient requiring urgent admission due to dehydration, decreased level of consciousness, lethargy and sign of respiratory failure. Each patient participated one time in the study. Sixty patients entered consecutively into the study. Thirty patients received nebulized 3% hypertonic saline as treatment group and 30 patients received nebulized 0.9% normal saline. Primary outcome were change in sum of RADI score and Yale clinical score and admission rate. Secondary outcome were duration length of hospital stay, intravenous fluid use, need to O2 therapy and remission of cough and wheezing.

General information

Acronym

N/A

IRCT registration information

IRCT registration number: **IRCT138903134096N1**
Registration date: **2013-08-12, 1392/05/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-08-12, 1392/05/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Bushehr university of medical sciences

Expected recruitment start date

2008-09-23, 1387/07/02

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Nebulized 3% hypertonic saline solution and 0.9% normal saline in2-24 m/o children with acute bronchiolitis.

Public title

Eeffect of Nebulized hypertonic saline solution on treatment of infant with viral bronchiolitis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: a total of infant (2 month to 24 month of age)with mild to moderate bronchiolitis seen in aliasghar tertiary care pediatric center ED in 2008-2010(fall & winter)were randomized to double blind treatment with nebulized salbutamol in either 3% saline or 0.9% saline. bronchiolitis: first or second episodes of respiratory distress with wheezing or sign of viral respiratory tract infections includes RR>60; 38ċ≤T; PR>180 or coryza. Exclusion criteria: pre-exiting cardiac or pulmonary disease; previous diagnosis of asthma or positive familial history of asthma; previous history of prematurity(GA<34w) or using ventilator at birth; severe illness that needed to immedietly hydration or decrease level of consciousness or letargia or respiratory failure & infants with RR>60; 38ċ≤T; PR>180 second or more episodes of respiratoye distress.
Age
To **2 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Bushehr University of Medical Sciences
Street address
Moallem Street
City
Bushehr
Postal code
Approval date
2008-09-04, 1387/06/14
Ethics committee reference number
31359

Health conditions studied

1

Description of health condition studied
Acute Viral bronchiolitis
ICD-10 code
J21
ICD-10 code description
Acute bronchiolitis

Primary outcomes

1

Description
change in sum of RADI score and YALE clinical score
Timepoint
at first & 30 minute later
Method of measurement
physical examination

2

Description
admission rate
Timepoint
30 minute
Method of measurement
physical examination

Secondary outcomes

1

Description
Intravenous fluid use
Timepoint
14 days
Method of measurement
physical examination

2

Description
length of stay
Timepoint
day of discharge
Method of measurement
physical examination

3

Description
oxygen use
Timepoint
day of discharge
Method of measurement
physical examination

4

Description
remission of cough and wheezing
Timepoint
1 mounth
Method of measurement
physical examination

Intervention groups

1

Description
In intervention group, nebulized 3% hypertonic saline 3 cc per 10 min till 3 dose, then countinue Q8h if patient addmited.
Category
Treatment - Other

2

Description
In control group, standard treatment with nebulized 0.9% saline 3cc Q10 min till 3 dose, then continue Q8h if patient admitted.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali-e- Asghar Pediatric Centre
Full name of responsible person
Dr Gissou Hatami
Street address
City
bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Bushehr University of Medical Sciences
Full name of responsible person
Dr Afshin ostovar
Street address
Bushehr University of Medical Sciences
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Bushehr 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

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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