Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison safety and efficacy of Phnylephrine with placebo in treatment of hospitalized children with bronchiolitis

Protocol summary

Summary

Acute bronchiolitis is the most common reason for hospitalization of infants during winter. A hypothesis for the effectiveness of epinephrine may be that it exerted an effect on overall infant respiratory mechanics by reducing nasal edema. We studied the effect of drop epinephrine (as a decongestant) with drop Nacl0.9% (as a placebo) on 100 patients between 1 to 12 months with the episode of wheezing, diagnosed as bronchiolitis who need to O2 therapy and admission in hospital. Before treatment the clinical condition (O2 saturation, respiratory rate, heart rate, retraction, dyspenea and wheeze) was evaluated. The first group (A) received routine treatment of bronchiolitis (O2 therapy, salbutamol spray and neubulizer) and also recieved drop phenyephrin 0.5% in supine position that remained in this position for 1 min. The second group (B) received routine treatment of bronchiolitis (O2 therapy, salbutamol spray and neubulizer) and also recieved drop NaCl 0.9% in supine position that remained in this position for 1 min. This is a double blind study. Both drops were colorless and smell less and labile as A and B. Thirty minutes after administration of drug and placebo, O2 saturation, respiratory rate, heart rate, retraction, dyspenea and wheeze were evaluated and scored.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108187371N1**
Registration date: **2011-09-29, 1390/07/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-29, 1390/07/07

Registrant information

Name
Marzieh Akbarpour
Name of organization / entity
Zahedan university of medical sceinces
Country
Iran (Islamic Republic of)
Phone
+98 911 135 0386
Email address
akbarpoorm@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison safety and efficacy of Phnylephrine with placebo in treatment of hospitalized children with bronchiolitis

Public title

New regimen of therapy in the treatment of Bronchiolitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ages 4 weeks to 12 months; clinical diagnosis of viral bronchiolitis as the primary reason for hospitalization; presence of an oxygen requirement and a minimum severity score of 1. Exclusion criteria: history

of chronic neurologic, heart, kidney, or lung disease; history of prematurity <34 weeks gestation; severity score of >10; use of nebulized albuterol or nebulized epinephrine within 4 hours of study enrollment; use of nasal phenylephrine or oxymetazoline within 12 hours of study enrollment; or “unstable” vital signs. “Unstable” vital signs are defined as heart rate >200 beats/min, blood pressure 2 standard deviations above or below the age appropriate mean, and respiratory rate above 80 breaths/min. The choice of maximum score is somewhat arbitrary but would exclude patients with all of the following: respiratory rate ≥70 breaths/min; intercostal, substernal and supraclavicular retractions; no feeding; and inspiratory and expiratory wheezing or diminished breath sounds.

Age
To **1 year** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Zahedan University of Medical Sceinces

Street address
Pardis of Zahedan university of medical sciences, Janat bloulovard

City
Zahedan

Postal code
2564-89

Approval date
2010-11-28, 1389/09/07

Ethics committee reference number
89-2564

Health conditions studied

1

Description of health condition studied
bronchiolitis

ICD-10 code
J20

ICD-10 code description
acute bronchiolitis

Primary outcomes

1

Description
respiratory distress

Timepoint
30 minutes after completion of therapy

Method of measurement
physical examination

Secondary outcomes

1

Description
Pulse rate

Timepoint
30 minutes after completion of therapy

Method of measurement
physical examination

2

Description
O2 saturation

Timepoint
30 minutes after completion of therapy

Method of measurement
physical examination

3

Description
dyspenea

Timepoint
30 minutes after completion of therapy

Method of measurement
physical examination

4

Description
retraction

Timepoint
30 minutes after completion of therapy

Method of measurement
physical examination

Intervention groups

1

Description
First group (A) received routine treatment of bronchiolitis and also received a drop phenyephrin 0.5% in supine position that remained in this position for 1 min.
Category
Treatment - Drugs

2

Description
The second group (B) received routine treatment of bronchiolitis and also recieved drop NaCl 0.9% in supine position that remained in this position for 1 min. Thirty minutes after administration of drug and placebo, O2 saturation, respiratory rate, heart rate, retraction, dyspenea and wheeze were evaluated and scored.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of pediatrics Infectious Diseases, Ali ebne Abitaleb Hospital
Full name of responsible person
Marzieh Akbarpour
Street address
Department of pediatrics Infectious Diseases, Ali ebne Abitaleb Hospital, Khalije Fars High way
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellory for Research, Zahedan University of Medical Sceiences
Full name of responsible person
Hamidreza Mahmoudzadeh_Sagheb
Street address
Daneshjo street, Zahedan University of Medical Sceiences
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellory for Research, Zahedan University of Medical Sceiences
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
Marzieh Akbarpour
Position
Resident of pediatrics disease
Other areas of specialty/work
Street address
Department of pediatrics Infectious Disease, Ali ebne Abitaleb Hospital, Khalije Fars High way
City
Zahedan
Postal code
Phone
+98 54 1341 1260
Fax
Email
akbarpoorm@zaums.ac.ir , Pardis_10107@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Gholamreza Soleimani
Position
Assistant Professor of pediatrics infectious disease & head of the Department of pediatrics Disease
Other areas of specialty/work
Street address
Ali ebne Abiteleb Hospital, Zahedan University of Medical Sciences, Khalije Fars High way
City
Zahedan
Postal code
Phone
+98 54 1341 1260
Fax
Email
soleimanigh@zaums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Marzieh Akbarpour

Position
Resident of pediatrics disease

Other areas of specialty/work

Street address
Department of pediatrics Infectious Diseases, Ali ebne Abitaleb Hospital, Zahedan University of Medical Sciences, Khalije Fars High way

City
Zahedan

Postal code

Phone
+98 54 1341 1260

Fax

Email
akbarpoorm@zaums.ac.ir , Pardis_10107@yahoo.com

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