

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 NaCl 0.9% (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, dyspnea and wheeze) was evaluated. The first group (A) received routine treatment of bronchiolitis (O2 therapy, salbutamol spray and nebulizer) and also received drop phenylephrine 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 nebulizer) and also received 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, dyspnea 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 sciences

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 Sciences

Street address

Pardis of Zahedan university of medical sciences, Janat bloulevard

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**

dyspnea

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, dyspnea 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, Khaliye Fars High way

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

Hamidreza Mahmoudzadeh_Sagheb

Street address

Daneshjo street, 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, 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

Marzieh Akbarpour

Position

Resident of pediatrics disease

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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

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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