Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Protocol summary

Summary

This study is designed to compare the effects of hypertonic saline 5 and 7% in the treatment of bronchiolitis in infants aged 2 months to 2 years. The study population will be 90 children aged 2 to 24 months with viral bronchiolitis admitted to Ardabil Buali hospital. Patients will be entered in this study with block randomization method of sampling and they will be divided into three groups of 30 people. This will be a double blind study namely both the subjects participating and the researchers will be unaware of medication type. Inclusion criteria are first or second episode of respiratory distress with wheezing and diagnosis of viral bronchiolitis based on the standard definition of bronchiolitis. Exclusion criteria are history of previous wheezing attacks more than 2 times, heart and lung disease, immunodeficiency, Down syndrome, metabolic diseases, use of mechanical ventilation, positive family history of asthma, and Patients who are critically ill. The first group will be treated with 0.15 mg/kg adrenaline along with hypertonic saline 5%, The second group will be treated with 0.15 mg/kg adrenaline along with hypertonic saline 7%, and the third group as the control group will be treated with the standard treatment, namely, 0.15 mg/kg adrenaline along with normal saline 0.9%. For all patients in the three groups, clinical symptoms (cough, wheezing, respiratory rate, heart rate, fever, crackles, oxygen saturation) and length of hospital stays will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090717843N5**
Registration date: **2015-12-09, 1394/09/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-12-09, 1394/09/18

Registrant information

Name
Adel Ahadi
Name of organization / entity
Ardabil University of Medical Sciences
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Public title

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: first or second episode of respiratory distress; wheezing; diagnosis of viral bronchiolitis based on the standard definition of bronchiolitis. Exclusion criteria: History of previous wheezing attacks more than 2 times; heart and lung disease; immunodeficiency; Down syndrome; metabolic diseases; use of mechanical ventilation; positive family history of asthma; and Patients who are critically ill.

Age

From **2 months** old to **2 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Research samples will be divided into three equal groups using block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, daneshgah Street, Ardabil.

City

Ardabil

Postal code

Approval date

2015-08-08, 1394/05/17

Ethics committee reference number

IR.ARUMS.REC.1394.19

Health conditions studied

1

Description of health condition studied

Acute bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes

1

Description

Oxygen Saturation

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Using pulse oximetry

2

Description

Respiratory rate

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

counting the number of breaths for one minute

3

Description

Heart rate

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

counting the number of heartbeats for one minute

4

Description

Fever

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Using a thermometer

5

Description

Crackles

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Examination

6

Description
cough duration
Timepoint
Every 6 hours for 24 hours after admission, and then once a day until discharge
Method of measurement
Patient observation and counting days till fully recover from cough

7

Description
Wheezing duration
Timepoint
Every 6 hours for 24 hours after admission, and then once a day until discharge
Method of measurement
Physical examination

8

Description
duration of hospital stay
Timepoint
Since the start of admission until discharge
Method of measurement
Counting the days of hospitalization

Secondary outcomes

empty

Intervention groups

1

Description
First group: 10 mL of 5% hypertonic saline with 0.15 mg/kg adrenaline
Category
Treatment - Drugs

2

Description
Second group: 10 mL of 7% hypertonic saline with 0.15 mg/kg adrenaline
Category
Treatment - Drugs

3

Description
Third group: standard treatment: 10 mL of 0.9% normal saline with 0.15 mg/kg adrenaline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali Hospital
Full name of responsible person
Dr Adel Ahadi
Street address
Bu-Ali Hospital, Saheli street, Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ardabil University of Medical Sciences
Full name of responsible person
Dr Shahram Habibzadeh
Street address
Ardabil University of Medical Science, Daneshgah Street, Ardabil
City
Ardabil
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 of Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Fatemeh Amani
Position
Medical Resident
Other areas of specialty/work
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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Adel Ahadi

Position

Pediatrics Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Fatemeh Amani

Position

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Other areas of specialty/work

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Email

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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