Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A randomized clinical trial to compare efficacy of nebulized hypertonic saline and normal saline in Length of hospital stay and severity score in children with acute bronchiolitis

Protocol summary

Study aim

Compaision the efficacy of nebulized hypertonic(3%, 5% and 7%) saline with normal saline in infants hospitalized with acute bronchiolitis

Design

120 children with moderate to severe bronchiolitis randomly assigned into four groups to receive nebulized normal saline(group A), saline 3%(group B), saline 5% (group C) and saline 7% (group D).

Settings and conduct

The study was done in emergency department of children hospitals in Isfahan. For each patient a vial labeled with a code was selected by chance and no one(parents of the patient, evaluators, analyzator) knew about content of the vial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: any infant from 1-24 months old with acute onset of respiratory distress and presence of wheezing on examination Exclusion criteria: evidence of atopy; history of prematurity (birth before 34 weeks or equal to); history of wheezing; history of previous bronchodilators or glucocorticoids use; loss of consciousness; history of chronic heart, pulmonary, neurologic, oncologic and immunologic disease.severe respiratory distress; respiratory failure requiring intubation or ICU admission Early discharge (less than 24 hours from admission) , need for intubation or ICU care in the course of disease

Intervention groups

infants with bronchiolitis treated with nebulized normal saline infants with bronchiolitis treated with nebulized 3% saline infants with bronchiolitis treated with nebulized 5% saline infants with bronchiolitis treated with nebulized 7% saline

Main outcome variables

Length of hospital stay (as primary outcome) and the use of oxygen, temperature, oxygen saturation (SPO2), pulse rate (PR), respiratory rate (RR) and bronchiolitis severity score (BRAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141201020175N3**
Registration date: **2018-03-02, 1396/12/11**
Registration timing: **retrospective**

Last update: **2018-03-02, 1396/12/11**
Update count: **0**

Registration date

2018-03-02, 1396/12/11

Registrant information

Name

Mohsen Reisi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-06-05, 1394/03/15

Actual recruitment start date
2015-11-22, 1394/09/01
Actual recruitment end date
2016-06-04, 1395/03/15
Trial completion date
empty

Scientific title
A randomized clinical trial to compare efficacy of nebulized hypertonic saline and normal saline in Length of hospital stay and severity score in children with acute bronchiolitis

Public title
Efficacy of hypertonic saline in acute bronchiolitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
acute onset of respiratory distress prodromal respiratory symptoms presence of wheezing on examination severity score (BRAS) equal five or more infants 1-24 months old
Exclusion criteria:
history of atopy history of prematurity (birth before 34 weeks or equal to) history of wheezing history of previous use of bronchodilators or glucocorticoids use loss of consciousness history of chronic heart, pulmonary, neurologic, oncologic and immunologic disease
Age
From **1 month** old to **2 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Actual sample size reached: **127**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation was done by using a computer-generated list of random numbers to identify 1 of 4 codes identifying 1 of 4 different 100-mL bags of sterilely prepared blinded study solution containing 7%, 5%, 3%, or 0.9% saline.
Blinding (investigator's opinion)
Triple blinded
Blinding description
All the vials containing normal saline and different degree of hypertonic saline were labeled by a number code and for each patient one code would be selected by chance for treatment. Non of the parents of the patients(patients are infants), health care providers, physicions evaluating BRAS score before and after intervention, data collectors and outcome assessors knows the density of the each vial.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan university of medical science, Hezarjarib street, Azadi square
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2015-11-22, 1394/09/01
Ethics committee reference number
IR.MUI.REC.1394.3.242

Health conditions studied

1

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

Primary outcomes

1

Description
Bronchiolitis respiratory assessment score (BRAS)
Timepoint
Before intervention and then every 4 hours
Method of measurement
Bronchiolitis respiratory assessment score (BRAS)

2

Description
length of hospital stay
Timepoint
At discharge

Method of measurement
Patient record

Secondary outcomes

1

Description
Respiratory rate
Timepoint
Before intervention and then every 4 hour
Method of measurement
observation

2

Description
Temperature
Timepoint
Before intervention and then every 4 hour
Method of measurement
Thermometer

3

Description
Heart rate
Timepoint
Before intervention and then every 4 hour
Method of measurement
determining pulse rate by use a chronometer

4

Description
O2 saturation
Timepoint
Before intervention and then every 4 hour
Method of measurement
pulse oximeter

Intervention groups

1

Description
Nebulize of 4 mL normal saline(0.9%) with 1.5 mL of epinephrine (1 /1000) through the mouth mask with 4 L / min oxygen; every 4 hours
Category
Treatment - Drugs

2

Description
Intervention group: Nebulize of 4 mL hypertonic saline(3%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours
Category
Treatment - Drugs

3

Description
Intervention group: Nebulize of 4 mL hypertonic saline(5%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours
Category
Treatment - Drugs

4

Description
Intervention group: Nebulize of 4 mL hypertonic saline(7%) with 1.5 mL of epinephrine through the mouth mask with oxygen; every 4 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Dr. Mohsen Reisi
Street address
Imam Hossein hospital, Imam Khomeini street, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mohsen Reisi
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Vice-chancellor of research, Isfahan University of Medical Sciences, Isfahan University of Medical Sciences, Hezarjarib street, Isfahan
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Email

international@mui.ac.ir

Web page address

https://mui.ac.ir/

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, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Vice-chancellor of research of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Reisi

Position

Pediatric pulmonologist, Assistant professor of Isfahan University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Child Growth and Development Research Center, Pediatric Pulmonology Department, Research Institute o

Full name of responsible person

Dr. Mohsen Reisi

Position

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Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Narges Afkande

Position

Pediatric specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available