Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of salbutamol and inhaled epinephrine and 5% hypertonic saline on reducing the severity of symptoms and duration of hospitalization of infants with bronchiolitis

Protocol summary

Study aim

Determining the effect of 5% salbutamol, epinephrine and saline hypertonic saline on the treatment of infants with bronchiolitis

Design

Clinical trial with three intervention groups, with parallel groups, double-blind, randomized, phase 3 on 45 infants. The Randomizer Software will be used for randomization.

Settings and conduct

Eligible infants after randomization were divided into three groups and the first group was 2.5 mg / kg body weight of salbutamol every 4 hours via nebulizer and the second group epinephrine via nebulizer at 0.5 mg / kg, and the third group of 5% Nacl at 3 cc in 0, 30 and 60 minutes

Participants/Inclusion and exclusion criteria

In this study, infants from 2 months to 24 months referred to Taleghani Educational and Medical Center who have symptoms of bronchiolitis and a respiratory score of 4 or higher based on Pediatric respiratory severity will be included. In contrast to infants born prematurely and hospitalized during the first two months of life, people with a history of chronic cardiopulmonary disease or hypersensitivity and drug reactions to salbutamol, epinephrine, and hypertonic saline, or those before Hospitalized for bronchodilators and corticosteroids will not be included in the study

Intervention groups

In this study, there are three intervention groups: group A users of inhaled salbutamol, group B users of inhaled epinephrine and group C users of inhaled hypertonic saline solution.

Main outcome variables

Severity of clinical symptoms including respiratory distress, skin color, general mood, number of breaths, body temperature, and auscultation by physician

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049210N1**
Registration date: **2020-11-22, 1399/09/02**
Registration timing: **prospective**

Last update: **2020-11-22, 1399/09/02**
Update count: **0**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Lobat Shahkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3222 7720

Email address

lobatshahkar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-25, 1399/09/05

Expected recruitment end date

2021-03-25, 1400/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of salbutamol and inhaled epinephrine and 5% hypertonic saline on reducing the severity of symptoms and duration of hospitalization of infants with bronchiolitis

Public title
Comparing the effects of nebulized salbutamol epinephrine and 5 hypertonic saline on lowering theseverity of symptoms in infant

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
pediatric respiratory severity score>=4 history of lower respiratory tract infections
wheezing,cough,cyanosis,spo2<90, fever age 2-24 month

Exclusion criteria:
drug reaction to salbutamol or epinephrine or hypertonic salin history of chronic cardiopulmonary disease preterm labor histroy of admision in age 0-2 month history of treatment with bronchodilator agents history of corticosteroid administration

Age
From **2 months** old to **24 months** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining informed consent from the parents of eligible infants, their allocation to each of the three groups receiving salbutamol inhaler (a), inhaler epinephrine (b) and saline recipient Inhalation hypertension (c) will occur randomly. For this purpose, the Randomizer Software will be used. based on the software output, the enterance sequence of participants will be written in advance by one of the members of the research team on cards with the letters a, b, and c and will be placed in sealed and numbered envelops. Once the eligibility of the infants is determined based on the inclusion and exclusion criteria, the numbers listed on the envelope will be determined in each of the groups.For example, for the first infant, envelope number 1 is opened and according to the letter in that group, the intervention will be specified and the desired intervention will be applied. Due to the fact that the sequence of entry of individuals by a person other than the person responsible for the intervention will be specified and placed in sealed envelopes, the process of entry of infants into each of the intervention groups will remain secret until the envelopes are opened.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the infant's parents, the person responsible for the intervention, and the person evaluating the outcome of the intervention will be kept unaware of how people are placed in the groups. In this way, the process of entering the groups will be determined in advance by one of the members of the research team and will be placed in numbered envelopes in the package. For this reason, when the infant is found to be eligible according to the inclusion criteria, the person responsible for the intervention (first physician) and the parents will be unaware of the type of intervention received (three intervention groups).After obtaining the consent of one of the envelopes, the numbers will be opened in order, and only at this stage it will be determined in which group the child will be placed. It should be noted that in this study, infants will be visited by two independent physicians. The first physician after assigning the child to the groups to apply the intervention and the second physician 24 and 48 hours after the intervention to evaluate the response to treatment. For this reason, both the intervention practitioner and the physician are responsible for evaluating the outcome of the intervention (response to treatment) and are unaware of the allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
Hircan Blvd., at the beginning of Shast Kola Road, Falsafi Educational Campus of Golestan University of Medical Sciences

City
Gorgan

Province
Golestan

Postal code
4934174515

Approval date
2020-10-04, 1399/07/13

Ethics committee reference number
IR.GOUMS.REC.1399.222

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
Primary Outcome: Clinical signs including severity of respiratory distress, wheezing, skin color, general mood, respiratory rate, body temperature, and lung murmur
Timepoint
Before the intervention and 24 and 48 hours after the intervention
Method of measurement
Based on the score obtained from the pediatric respiratory severity score and observation

Secondary outcomes

1

Description
The length of hospital stay is the number of days a patient receives medication, parenteral fluid, and oxygen for bronchiolitis
Timepoint
Once at the end of the treatment period
Method of measurement
Count the days the patient receives medication, parenteral fluid, and oxygen for bronchiolitis

Intervention groups

1

Description
Recipients of inhaled salbutamol. Nebulizer treated with salbutamol 2.5 mg / kg every 4 hours via nebulizer and 48 to 24 hours after hospitalization
Category
Treatment - Drugs

2

Description
Intervention group:Recipients of inhaled epinephrine via nebulizer at 0.5 mg / kg and 48 to 24 hours after hospitalization
Category
Treatment - Drugs

3

Description
Intervention group: Recipients of inhaled hypertonic saline (5% Nacl) at 3 cc at 0, 30 and 60 minutes
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Medical Educational Center
Full name of responsible person
Lobat Shahkar
Street address
Azadi St., Janbazan Boulevard, In Front Of Janbaz 22
City
Gorgan
Province
Golestan
Postal code
4916668197
Phone
+98 17 3222 7720
Fax
+98 17 3225 6440
Email
Taleghani@goums.ac.ir
Web page address
http://goums.ac.ir/index.php?slc_lang=fa&sid=31

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohamadreza Honarvar
Street address
Hyrkan Boulevard, at The Beginning of ShastKola Road, Falsafi Educational Campus, Deputy of Research and Technology
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 1660
Fax
+98 17 3245 1657
Email
Honarvar@goums.ac.ir
Web page address
http://goums.ac.ir/index.php?slc_lang=fa&sid=12
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Seyed Ali Mosavikhosravi
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Taleghani Medical Educational Center, Janbazan Ave
City
Gorgan
Province
Golestan
Postal code
4918668197
Phone
+98 17 3224 7622
Email
dr.ali.m363@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Lobat Shahkar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Taleghani Hospital Janbazan St
City
Gorgan
Province
Golestan
Postal code
4916668197
Phone
+98 17 3222 7720
Email
Lobatshahkar@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Seyed Ali Mosavikhosravi
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Taleghani Medical Educational Center, Janbazan Ave.
City
Gorgan
Province
Golestan
Postal code
4918668197
Phone
+98 17 3224 7324
Email
dr.ali.m363@gmail.com

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available