Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Investigating the comparison therapeutic effect of 5% saline versus 3% in the hospitalized patient with Acute Bronchiolitis.

Protocol summary

Study aim
Determination of the comparison therapeutic effect of 5% saline versus 3% in the hospitalized patient with Acute Bronchiolitis.

Design
The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized.

Settings and conduct
This study was conducted to evaluate the effect of 5% and 3% nebulizer saline in patients with acute bronchiolitis admitted to Heshmatiyeh Hospital in Sabzevar city. In this study, participants and those who evaluated the outcome in children were unaware of how children were grouped. Children are randomly assigned to the first intervention group (Nebulizer Saline 5%) and second intervention group (Nebulizer Saline 3%). The response to treatment is evaluated using MRAS (modified respiratory assessment score) at the beginning of the study (before the intervention) and daily until discharge.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 1 to 24 months with moderate to severe Bronchiolitis and clinical scores >= 4
Exclusion criteria: The presence of underlying disease (cystic fibrosis, congenital heart disease, immune deficiency), Get antibiotics before studying, Get Cortisone Inhaled and Systemic Recent, Use of bronchodilators, History of immaturity and gestational age less than 32 weeks, Chronic pulmonary disease, and History of NICU admission

Intervention groups
First intervention group: Patients in this group received 0.15 mg/kg Salbutamol and 5 cc nebulizer saline 5% and 8 liters of oxygen per minute while receiving nebulizers.
Second intervention group: Patients in this group received 0.15 mg/kg Salbutamol and 5 cc nebulizer saline 3% and 8 liters of oxygen per minute while receiving nebulizers.

Main outcome variables
Determine the Modified Respiratory Assessment Score (MRAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181006041252N4**
Registration date: **2018-12-31, 1397/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**
Update count: **0**

Registration date
2018-12-31, 1397/10/10

Registrant information

Name
Mohammad Sahebkar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-26, 1397/10/05

Expected recruitment end date
2019-02-24, 1397/12/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the comparison therapeutic effect of 5% saline versus 3% in the hospitalized patient with Acute Bronchiolitis.

Public title
Investigating the comparison therapeutic effect of 5% saline versus 3% in the hospitalized patient with Acute Bronchiolitis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 1 to 24 months with moderate to severe Bronchiolitis and clinical scores >= 4

Exclusion criteria:
The presence of underlying disease (cystic fibrosis, congenital heart disease, immune deficiency) Get antibiotics before studying Get Cortisone Inhaled and Systemic Recent use of bronchodilators History of immaturity and gestational age less than 32 weeks Chronic pulmonary disease History of NICU admission

Age
From **1 month** old to **24 months** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was conducted based on a permutation block, Accordingly, 47 blocks were allocated to patients, in each block, 2 were from following groups, treatment group A and group B. Eventually, after completing the blocks, Group A and B were treated with Nebulizer Saline 5% and Nebulizer Saline 3%, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each person will be assigned a study code A and B, which will only be known to the researcher of the type of groups. The person evaluating the outcome and the participants are unaware of the groups. It should be noted that saline 5% and 3% are similar in terms of appearance, color, and packaging.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913114

Approval date
2018-12-17, 1397/09/26

Ethics committee reference number
IR.MEDSAB.REC.1397.077

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
Determine the Modified Respiratory Assessment Score (MRAS)

Timepoint
At the beginning of the study (before the intervention) and daily until discharge

Method of measurement
Using the modified respiratory assessment score

Secondary outcomes

1

Description
Determine the respiratory sounds (Vising)

Timepoint
At the beginning of the study (before the intervention) and daily until discharge

Method of measurement
Auscultation of the lungs with Stethoscope

2

Description
Respiratory Rate
Timepoint
At the beginning of the study (before the intervention) and daily until discharge
Method of measurement
The number of chest or abdominal cramps in 15 seconds or 1 minute

3

Description
Determine the level of peripheral capillary oxygen saturation (SPO2)
Timepoint
At the beginning of the study (before the intervention) and daily until discharge
Method of measurement
Pulse Oximeter or Oxygenometer

Intervention groups

1

Description
Intervention group: Patients in this group received 0.15 mg/kg Salbutamol and 5 cc nebulizer saline 5% and 8 liters of oxygen per minute while receiving nebulizers.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in this group received 0.15 mg/kg Salbutamol and 5 cc nebulizer saline 3% and 8 liters of oxygen per minute while receiving nebulizers.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmatiyeh hospital
Full name of responsible person
Nasrin Amini Fard
Street address
Heshamatiyeh Hospital, Asadabady Ave., Sabzevar Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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
Not applicable

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
No - There is not a plan to make this available

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