

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 51 4401 8337

Email address

sahebkar@medsab.ac.ir

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

Heshmatiyeh Hospital, Asadabady Ave., Sabzevar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

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

Dr. Alireza Asadi

Position

Assistant Professor

Latest degree

Subspecialist

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

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