

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The comparison of efficacy of nebulized Ventolin and Pulmicort and normal saline in treatment of children under 2 years old with bronchiolitis

Protocol summary

Study aim

The aim of this study is to comparison of efficacy of nebulized ventolin and pulmicort and normal saline in treatment of children under 2 years old with bronchiolitis.

Design

This is a controlled single-blinded clinical trial study will be conducted on 100 children with the diagnosis of bronchiolitis. After coordination and obtaining informed consent, the patients will be randomly assigned into 3 groups of ventolin, pulmicort and normal saline.

Settings and conduct

This single-blinded clinical trial study will be conducted in Aboozar Hospital, Ahvaz, Iran. The patients under the age of 24 months with the diagnosis of bronchiolitis will be randomly divided into 3 groups. In Group 1: patients received nebulized ventolin, in Group 2: the patients received pulmicort, and in Group 3: the patients received nebulized normal saline.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children less than 24 months, definitive diagnosis of bronchiolitis, parents' consent to participate in the study; Exclusion criteria: Chronic heart and lung disease (heart failure or pulmonary cyst), immunodeficiency, metabolic or neurological disorders, birth below 34 weeks, use of ventilator in neonatal period, receiving systemic corticosteroid or antibiotic during hospitalization.

Intervention groups

In first group, Ventolin nebulizer (Salbutamol) 0.15 mg/kg every 4 hours will be administered by nebulizer. In second group, Budesonide (Pulmicort) 125 mg 2 twice a day (morning and evening) will be administered. In third group, normal saline nebulizer (3 ml normal saline 0.9%) every 4 hours will be administered.

Main outcome variables

The Oxygen saturation, Symptom severity (clinical score) and length of recovery will be compared between the 3 groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200209046435N1**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **prospective**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Mahsa Abdolazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3001 3374

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy of nebulized Ventolin and Pulmicort and normal saline in treatment of children under 2 years old with bronchiolitis

Public title

The efficacy of Ventolin and Pulmicort and normal saline in treatment of bronchiolitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children less than 24 months, , Definitive diagnosis of bronchiolitis Parents' consent to participate in the study

Exclusion criteria:

Chronic heart and lung disease (heart failure or pulmonary cyst) Immunodeficiency Metabolic or neurological disorders Birth below 34 weeks Use of ventilator in neonatal period Receiving systemic corticosteroid or antibiotic during hospitalization

Age

To **24 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into three groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the three treatment groups before starting intervention. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment

Blinding (investigator's opinion)

Single blinded

Blinding description

Intervention (receiving normal saline or Ventolin or Pulmicort) and patient evaluation will be carried out by a physician who is aware of treatment groups. The patients parents and statistical analyzer will not know about patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.AJUMS.REC.1398.807

Health conditions studied**1****Description of health condition studied**

Bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes**1****Description**

Symptom severity (clinical score)

Timepoint

Everyday, before intervention and during the intervention

Method of measurement

According to Respiratory Distress Assessment Index (RDAI)

2**Description**

Duration of symptom recovery

Timepoint

Daily, before intervention until the end of intervention

Method of measurement

Duration of recovery from wheezing and cough based on clinical examination

3**Description**

Oxygen saturation

Timepoint

Every day, before intervention and during the

intervention
Method of measurement
Using pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ventolin nebulizer (Salbutamol) 0.15 mg/kg every 4 hours will be administered by nebulizer.

Category

Treatment - Drugs

2

Description

Intervention group: Budesonide (Pulmicort) 125 mg 2 twice a day (morning and evening) will be administered.

Category

Treatment - Drugs

3

Description

Control group: normal saline nebulizer (3 ml normal saline 0.9%) every 4 hours will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aboozar Hospital

Full name of responsible person

Mahsa Abdollahzade

Street address

Aboozar Hospital, Tohid Blv., Zeytun Karmandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz 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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farhad Abolnezhadian

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

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Position

Resident

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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