Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 diorders, 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 Abdolahzadeh

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 diorders 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

Mohammad Badavi

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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

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Abdolahzadeh

Position
Resident

Latest degree
Medical doctor

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