

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of inhaled beta2 agonist (Ventolin) in the treatment of bronchiolitis in children

Protocol summary

Study aim

Determining the effect of inhaled beta2 agonist (Ventolin) in the treatment of bronchiolitis

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The study will be conducted at Shahid Beheshti Hospital in Kashan and will continue until discharge from the hospital. Finally, the patients were divided into 2 groups. Standard treatment group: supportive treatment including oxygen and serum therapy is prescribed. Intervention group B: participants in this group, in addition to supportive therapy such as oxygen supplementation and receiving serum, are treated with a salbutamol nebulizer of 0.15 mg/kilogram of body weight. The production of GSK company, which will be prepared in coordination with the hospital pharmacy, will be given once every 20 minutes for an hour and then every 4 hours along with routine treatment. Participants, researchers, and outcome assessors were blinded in this study.

Participants/Inclusion and exclusion criteria

Entry criteria: age less than 2 years; Exit criteria: who will not be hospitalized due to the low severity of the disease Age less than 1 month or more than 2 years Immunodeficiency Congenital heart,lung disease Severe and mild severity of the disease

Intervention groups

The participants in this group, in addition to supportive treatment such as oxygen supplementation and receiving serum, are treated with a salbutamol nebulizer of 0.15 mg per kilogram of body weight produced by GSK nebulizers, which will be prepared in coordination with the hospital pharmacy, first once every 20 minutes until One hour and then every 4 hours along with routine treatment

Main outcome variables

Respiratory rate, blood oxygen saturation, whizzing, retraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230413057899N1**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

mahsa sadat nezam taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5545 3757

Email address

m.nezamtaheri1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of inhaled beta2 agonist (Ventolin) in the treatment of bronchiolitis in children

Public title
the effect of Ventolin in the treatment of bronchiolitis in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age less than 2 years
Exclusion criteria:
Patients who will not be hospitalized due to the low severity of the disease Immunodeficiency Congenital heart disease Congenital lung disease Severe and mild severity of the disease

Age
From **1 month** old to **2 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done in blocks and a table will be prepared by computer and Excel software. The blocks will be binary combinations of AB, BA, BB, and AA, where each of the letters A and B will indicate standard treatment and Ventolin treatment, respectively. The patients were finally divided into 2 groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients receive their treatment (intervention or control group) while receiving oxygen therapy (Ventolin nebulizers in hospital-grade nebulizer masks), which are coded. Coding is done by one of the colleagues of the project, and the doctor, evaluator, and patient are blinded to how the patients are coded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Medicine & Faculty of Dentistry- Kashan University of Medic

Street address

56 Hekmat, Qutb Rawandi Boulevard, Kashan, Isfahan Province

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.109

Health conditions studied

1

Description of health condition studied

Bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes

1

Description

Respiratory rate

Timepoint

1 hour and a half after starting the study

Method of measurement

Physical examination

2

Description

oxygen saturation

Timepoint

1 hour and a half after starting the study

Method of measurement

Pulse oximetry device

3

Description

Whizzing

Timepoint

1 hour and a half after starting the study

Method of measurement

Physical examination

4

Description

Retraction

Timepoint

1 hour and a half after starting the study

Method of measurement

Physical examination

Secondary outcomes

1

Description

Length of hospitalization

Timepoint

end of study

Method of measurement

number of days

Intervention groups

1

Description

The participants in this group, in addition to supportive treatment such as oxygen supplementation and receiving serum, are treated with a salbutamol nebulizer 0.15 mg per kilogram of body weight produced by GSK nebulizers, which will be prepared in coordination with the hospital pharmacy, first once every 20 minutes until One hour and then every 4 hours along with routine treatment

Category

Treatment - Drugs

2

Description

Control group: supportive treatment including oxygen therapy and serum therapy is prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mehsa Sadat Nezam Taheri

Street address

Allameh Qutb Ravandi Blvd, Kashan, Isfahan Province,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Mahsa sadat Nezam taheri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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22 bahman ave. tohid 9 str. no.5

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Mahsa sadat Nezam taheri
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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Confirming the activities of researchers in academic and scientific institutions

From where data/document is obtainable

Mehsa Sadat Nizam Taheri
m.nezamtaheri1369@gmail.com

What processes are involved for a request to access data/document

Formal request for access to data after 6 months of publication of the study The data will be sent to the sent email within one month after the request

Comments