Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of the effect of comparing bronchodilators with corticosteroids and bronchodilators in children with bronchiolitis

Protocol summary

Study aim
Determining and comparing the effects of bronchodilators with corticosteroids and bronchodilators in patients referred to bronchiolitis to the specialized clinic of Imam Khomeini Hospital in Ilam in 1300-1499

Design
This study is a double-blind randomized clinical trial in which all infants aged 2 to 24 months with the first Weiss attack who are diagnosed with bronchiolitis need to be hospitalized and receive oxygen and have a minimum score of 4 according to the CBSS criteria table. 30 people in each group, the total volume of 60 people was calculated assuming equality of variance.

Settings and conduct
This study is a clinical trial study in which the study population is all children aged 24-24 months who have referred to the specialized pediatric clinic of Imam Khomeini Hospital in Ilam during the year with a diagnosis of viral bronchiolitis.

Participants/Inclusion and exclusion criteria
This study is a double-blind randomized clinical trial in which all infants aged 2 to 24 months with the first Weiss attack who are diagnosed with bronchiolitis need to be hospitalized and receive oxygen.

Intervention groups
Infants aged 2 to 24 months with a diagnosis of bronchiolitis

Main outcome variables
Oxygen saturation, pulse rate and respiration rate, RDA Score and Clinical Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220225054120N1**
Registration date: **2022-05-11, 1401/02/21**
Registration timing: **registered_while_recruiting**
Last update: **2022-05-11, 1401/02/21**
Update count: **0**

Registration date
2022-05-11, 1401/02/21

Registrant information

Name
Zahra Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 4444 2476

Email address
z.maleki69@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-07, 1401/02/17

Expected recruitment end date
2022-08-11, 1401/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of comparing bronchodilators with corticosteroids and bronchodilators in children with bronchiolitis

Public title
Evaluation of the effect of comparing bronchodilators with corticosteroids and bronchodilators in children with bronchiolitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria Based on the standard definition of bronchiolitis, the first or second episode of respiratory distress with wheezing and clinical evidence of viral respiratory infection such as body temperature 38 ° C and above, tachypnea and tachycardia or Coryza symptoms.

Exclusion criteria:

History of more than two episodes of respiratory distress in the past. Chronic heart and lung disease Immunodeficiency Down Syndrome Metabolic or neurological illness History of prematurity (less than 34 weeks of Gesteitional age) Use of mechanical ventilation in infancy Positive family history of utopia Ill child in need of hospitalization due to dehydration, decreased level of consciousness, lethargy or symptoms of respiratory failure

Age

From **2 months** old to **24 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, the researcher uses the main entry and exit conditions of the study to prepare a list of eligible patients to participate in this study. If you wish and consent to participate in this research study, general information and written consent. Will be taken from patients' families. Then 60 patients with bronchiolitis are randomly divided into control group or intervention group using block randomization method by hiding random allocation. The control group will receive only the standard treatment protocol, but the intervention group will receive corticosteroids in addition to the standard treatment protocol.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug (intervention or comparison group) in sealed packets encoded. The coding is done by one of the project partners and the doctor, the evaluator and the patient are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

Street address

Ilam, Bangangab, Research Blvd., Ilam University of Medical Sciences,

City

ilam

Province

Ilam

Postal code

٦٩٣٩١٧٧١٤٣

Approval date

2022-01-08, 1400/10/18

Ethics committee reference number

IR.MEDILAM.REC.1400.203

Health conditions studied

1

Description of health condition studied

Bronchiolitis

ICD-10 code

J11.1

ICD-10 code description

Influenza due to unidentified influenza virus with other respiratory manifestations

Primary outcomes

1

Description

All infants 2 to 24 months of age with the first Wise attack who are diagnosed with bronchiolitis need to be hospitalized and receive oxygen

Timepoint

After initial evaluation (on arrival), second evaluation (1 hour appointment) (1 dose of hydrocortisone ampoule, 5 mg per kg body weight and ventolin nebulizer at a dose of 0.15 mg per kg body weight (minimum dose) 2.5 mg and a maximum of 5 mg) and continue ventilation every 20 minutes for up to 3 doses, including monitoring of oxygen prevalence (using pulse oximetry), respiration rate, and pulse rate. In addition to oxygen saturation, Pulse rate and respiration rate, RDA Score and Clinical Score will also be checked and recorded

Method of measurement

CBSS table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group: hydrocortisone with Oxycort brand 5 mg per weight (one dose) and bronchodilator as ventolin or salbutamol at a dose of 0.15 mg per weight with an interval of 20 minutes, up to one hour in three times. / The second group only bronchodilator In the form of ventolin or salbutamol at a dose of 0.15 mg per weight at intervals of 20 minutes, up to one hour in three doses

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital of Ilam

Full name of responsible person
Dr. Jassem Mohammadi

Street address
Ilam, Ayatollah Heidari Blvd., Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Saeed Kazemi

Street address
ایلام، بانگجناب، بلوار پژوهش، دانشگاه علوم پزشکی ایلام،

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medcollege@medilam.ac.ir

Web page address
http://medicine.medilam.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ilam 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
Ilam University of Medical Sciences

Full name of responsible person
Zahra Maleki

Position
Resident Children

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

Street address
East Azarbaijan province, Kalibar city, Moallem street, Valfajr alley 2, No. 672

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Kaleibar

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Person responsible for scientific inquiries

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
No personal data are taken from the participants in our study

When the data will become available and for how long
دوره دسترسی 3 ماه پس از دفاع از پایان نامه شروع می شود

To whom data/document is available
After publishing the results, everyone has the right to access the data

Under which criteria data/document could be used
All students and university staff have a sense of using data for citation, not copying

From where data/document is obtainable
Access data via email to the first or responsible author

What processes are involved for a request to access data/document
It will be answered as soon as you receive the email and have enough time

Comments