Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of inhaled budesonide (Pulmicort) on children with acute asthma attack in patients referred to Ali Asghar Children's Hospital

Protocol summary

Study aim

Determining the effect of Pulmicort on the Cough rate ; Determining the effect of Pulmicort on the rate of wheezing; Determining the effect of Pulmicort on the duration of hospitalization; Determining the effect of Pulmicort on the Workup breathing; Determining the effect of Pulmicort on the side effects (palpitations, tremors) of children with acute asthma attacks.

Design

A clinical trial with the control group, phase 3, Double blinded, parallel-group design of 80 patients, randomized groups (Block form), the size of two control and intervention groups are equal

Settings and conduct

This study is a randomized clinical trial study. The place of work is Ali Asghar Children's Hospital. At the beginning of the study, all children with asthma attacks will be tested for asthma scores. They are then randomly (Block form) divided into two groups of tests and controls (an equal number in each group). All patients are treated with standard asthma treatment, including oxygen and beta-2 agonists and systemic corticosteroids, the first group receives inhale budesonide (Pulmicort), the second group receives normal saline (placebo). The follow-up of the patient will be 6, 12, 24, and 48 hours later. How to blind: Sealed envelope, doctor, and patient are blinded and the nurse is the triage or ward knows the information.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2 to 12 years; acute asthma attack; No other diseases; exclusion criteria: cardiology disease; taking steroid medications for the past 7 days.

Intervention groups

Control and Intervention groups: Children with acute asthma attacks Both groups received basic asthma treatment. The intervention group received budesonide nebulization and the control group received normal saline nebulization.

Main outcome variables

Cough rate; Weezing score; Workup Breathing; duration of hospitalization; possible complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042260N2**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Rozhin Pahlevani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4431 9829

Email address

pahlevan.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of inhaled budesonide (Pulmicort) on children with acute asthma attack in patients referred to Ali Asghar Children's Hospital

Public title

Evaluation of the effect of inhaled budesonide (Pulmicort) on children with acute asthma attack

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed as asthma by doctor Lack of other chronic and specific diseases Diagnosis as acute asthma attack by doctor Age range Between 2-12 years old

Exclusion criteria:

A child with heart disease Lack of willingness to participate in the study Have chronic lung disease other than asthma Children who have received specific steroid medications over the past 7 days

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization will be use and the number of two control and test groups will be equal so that in each group, 4, 8, 10, and 12 Blocks are used, and the volume of each group is 40, and in total will be 80 patients. Allocation Concealment: In sealed envelopes, a random sequence is mentioned on the envelope and given to the nurse, and the doctor and patient are not informed about the details.

Blinding (investigator's opinion)

Double blinded

Blinding description

The sealed envelope is in the hands of the nurse of the triage or ward for the selection of the drug or placebo, and is randomly assigned to the patients, respectively. The drug with a placebo is drawn in the same form by the triage nurse in the syringe and used in a nebulizer.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No4, Elahieh 19, Elahieh Complex, end of Kuhsar Blvd, shahran, tehran,Iran

City

Tehran

Province

Tehran

Postal code

1488874645

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.IUMS.FMD.REC.1399.145

Health conditions studied

1

Description of health condition studied

Acute asthma attack in pediatric

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Cough rate

Timepoint

6,12,24,48 hours after the interventions

Method of measurement

Based on mild / moderate / severe

2

Description

Weezing score

Timepoint

6,12,24,48 hours after the interventions

Method of measurement

Based on a score of 0 to 3/ without, in inhalation, in exhalation, Both

3

Description

workup Breathing

Timepoint
6,12,24,48 hours after the interventions
Method of measurement
Based on mild / moderate / severe

4

Description
Duration of hospitalization
Timepoint
The number of hospitalization days
Method of measurement
According to the number of days

5

Description
Respiratory rate
Timepoint
6,12,24,48 hours after the interventions
Method of measurement
Based on mild / moderate / severe

6

Description
possible complication
Timepoint
During the hospitalisation
Method of measurement
Based on drug side effects

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children with an acute asthma attack receive the basic treatment for an asthma attack and will also receive an inhaled budesonide (Pulmicort). Ventolin dose will be 0/03 ml (0/15 mg) per kg (minimum 0/5 ml [2/5 mg], maximum 0/1 ml [5 mg]) . Intravenous hydrocortisone dose will be 40 mg/kg /d, and the dose of Pulmicort will be 0/25 mg inhaled every 6 hours, up to 4 times a day for a maximum of 1 mg daily throughout the hospitalization period.
Category
Treatment - Drugs

2

Description
Control group: Children with an acute asthma attack receive the basic treatment for an asthma attack and will also receive a 3 cc normal saline as a placebo. Ventolin dose will be 0/03 ml (0/15 mg) per kg (minimum 0/5 ml [2/5 mg], maximum 0/1 ml [5 mg]) . Intravenous hydrocortisone dose will be 40 mg/kg /d.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali asghar children`s hospital
Full name of responsible person
Rozhin Pahlevani
Street address
No.4, Elahieh 19, Elahieh complex, End of koohsar Blvd., Shahran
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Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Abass Motevalian
Street address
fifth floor of the central headquarters ,Iran University of Medical Sciences, Shahid Hemmat Highway, Next to Milad Tower,Tehran
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Postal code
1449614535
Phone
+98 21 8670 2504
Fax
+98 21 8862 2307
Email
motevalian.a@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Rozhin Pahlevani

Position

Pediatric resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

This study will be performed as a clinical trial (Phase 3) and Double-Blinded type, in two groups of control and intervention and with drugs approved by the Food and Drug Administration and common in the pharmaceutical market, and the results can be shared.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers, doctors

Under which criteria data/document could be used

This study is a small-scale, pilot study, and is expected to be investigated with a bigger sample size after termination.

From where data/document is obtainable

Rozhin pahlevani's Email Addresses: Pahlevan.r@iums.ac.ir Rozhin.pahlevan@gmail.com Rozhin_p92Yahoo.com

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

Once the article is published, applicants can receive information about the data through the email addresses provided.

Comments