

# 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

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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

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fifth floor of the central headquarters ,Iran University of Medical Sciences, Shahid Hemmat Highway, Next to Milad Tower,Tehran

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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**

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

### Contact

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## Person responsible for updating data

### Contact

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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**