

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of epinephrine nebulizer with subcutaneous injection in patients with acute asthma attack: a randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of injectable adrenaline and nebulizer in children with acute asthma attack who did not respond to standard treatments.

##### Design

This study is a randomized, single-blind clinical trial. Considering the first error of 5% and the power of 80%, and including the dropout, the number of 33 people and a total of 66 people have been considered. A non-random sampling method was chosen after obtaining written informed consent

##### Settings and conduct

Children suffering from an acute attack referred to the emergency room of Akbar, Qaim or Dr. Sheikh Children's Hospitals, who did not respond to the initial stages of standard asthma treatment including bronchodilator oxygen, Atrovent, and injectable corticosteroids at appropriate doses, and due to the persistence of respiratory symptoms, the need to use Complementary drugs such as magnesium sulfate or adrenaline are administered under the subcutaneous injection of epinephrine or nebulized epinephrine. Two ampoules of epinephrine will be added to the appropriate volume for nebulization. It is done in the time interval before the visit and one hour after receiving subcutaneous epinephrine or epinephrine nebulization.

##### Participants/Inclusion and exclusion criteria

Children aged 2 to 14 years; children with severe and resistant asthma attacks that have not responded to standard asthma treatment in the early stages including: bronchodilator oxygen, Atrovent and intravenous corticosteroids.

##### Intervention groups

Children aged 2 to 14 years with severe asthma attacks who have not responded to standard treatments are compared with two methods of injectable adrenaline and nebulizer.

##### Main outcome variables

Number of breaths per minute according to age, vise

(inhaler) vise expiratory, ratio of inhalation to exhalation, use of secondary muscles of respiration, oxygen saturation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230606058389N1**

Registration date: **2023-07-10, 1402/04/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-10, 1402/04/19**

Update count: **0**

##### Registration date

2023-07-10, 1402/04/19

##### Registrant information

##### Name

Mohammad Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 935 879 4426

##### Email address

ghasemim12@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-06, 1402/04/15

##### Expected recruitment end date

2024-07-05, 1403/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of epinephrine nebulizer with subcutaneous injection in patients with acute asthma attack: a randomized clinical trial

**Public title**  
The effect of epinephrine nebulizer with subcutaneous injection in patients with acute asthma attack

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Children with acute asthma attacks referred to the emergency of Akbar's children, Qaem or Dr. Sheikh hospitals who have not responded to the initial stages of standard asthma treatment, including bronchodilator oxygen, Atrovent, and injectable corticosteroids with appropriate doses.  
**Exclusion criteria:**  
Children with asthma with conventional treatment response Children over 14 years old Children with asthma due to another side effect

**Age**  
From **2 years** old to **14 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **66**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Blocked randomization Exactly equal number of participants are included in the intervention and control group at consecutive but equal time intervals. And blocks of four will be used. The sequences will be placed in the envelopes in the package. The appearance of the envelopes is such that their contents cannot be seen from the outside. Then, one of the envelopes will be opened for each patient entered into the plan and based on the contents of the envelope, the patient will be entered into one of the control or intervention groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The sequences will be placed in the envelopes in the package. The appearance of the envelopes is such that their contents cannot be seen from outside. Then, one of the envelopes will be opened (in order) for each patient entered into the plan and based on the contents of the envelope, the patient will be entered into one of the control or intervention groups.

**Placebo**  
Not used

**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee of Mashhad University of Medical Sciences  
**Street address**  
Mashhad, Daneshgah Street, next to Hoizeh Cinema, Qorshi Building, Research and Technology Vice-Chancellor  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9138813944  
**Approval date**  
2021-04-24, 1400/02/04  
**Ethics committee reference number**  
IR.MUMS.MEDICAL.REC.1400.244

**Health conditions studied**

1

**Description of health condition studied**  
Status asthma  
**ICD-10 code**  
J45.902  
**ICD-10 code description**  
Unspecified asthma with status asthmaticus

**Primary outcomes**

1

**Description**  
Number of breaths per minute according to age,  
**Timepoint**  
The time interval before the visit and one hour after receiving subcutaneous epinephrine or epinephrine bolus. Patients will be visited and examined by the on-call resident during their hospitalization.  
**Method of measurement**  
Subcutaneous injection of epinephrine with a dose of 0.01 cc of 1.1000 solution or nebulization of epinephrine in the form of nebulization of two ampoules of epinephrine 1.1000 which will be placed after adding normal saline to the appropriate volume for nebulization.

## 2

### **Description**

Expiratory - inspiratory wheezing

### **Timepoint**

The time interval before the visit and one hour after receiving subcutaneous epinephrine or epinephrine bolus. Patients will be visited and examined by the on-call resident during their hospitalization.

### **Method of measurement**

Subcutaneous injection of epinephrine with a dose of 0.01 cc of 1.1000 solution or nebulization of epinephrine in the form of nebulization of two ampoules of epinephrine 1.1000 which will be placed after adding normal saline to the appropriate volume for nebulization.

## 3

### **Description**

Use of respiratory secondary muscles

### **Timepoint**

The time interval before the visit and one hour after receiving subcutaneous epinephrine or epinephrine bolus. Patients will be visited and examined by the on-call resident during their hospitalization.

### **Method of measurement**

Subcutaneous injection of epinephrine with a dose of 0.01 cc of 1.1000 solution or nebulization of epinephrine in the form of nebulization of two ampoules of epinephrine 1.1000 which will be placed after adding normal saline to the appropriate volume for nebulization.

## 4

### **Description**

Oxygen saturation according to the Pulmonary Index score table

### **Timepoint**

The time interval before the visit and one hour after receiving subcutaneous epinephrine or epinephrine bolus. Patients will be visited and examined by the on-call resident during their hospitalization.

### **Method of measurement**

The treatment steps for asthma symptoms will be carefully checked and recorded according to the pulmonary index score table. Then the symptoms will be checked until the end of the complete recovery and the time to reach this condition for both groups will be recorded in the checklist prepared for this purpose.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Children with an acute asthma attack that has not responded to standard treatments. Children with an acute attack referred to the emergency room of Akbar, Qaim or Sheikh Children's Hospitals who have not

responded to the initial stages of standard asthma treatment including bronchodilator oxygen, Atrovent, and injectable corticosteroids with appropriate doses, and due to the persistence of respiratory symptoms and wheezing Inclusion criteria are included in the treatment process. After obtaining written informed consent from parents or legal guardians and under subcutaneous injection of epinephrine with a dose of 0.01 cc of 1.1000 solution or epinephrine nebulization in the form of nebulization of two ampoules of epinephrine 1.1000 which after adding normal saline reached the appropriate volume for nebulization will be placed. The procedures will be performed under the supervision of the resident guard of the hospital and according to the standard instructions, which will be performed between the time of visit and one hour after receiving subcutaneous epinephrine. The stages of recovery of asthma symptoms will be checked and recorded according to the pulmonary index score table. Then the symptoms will be checked until the end of the complete recovery and the time to reach this condition for both groups will be recorded in the checklist prepared for this purpose.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Children with an acute attack of severe asthma and resistant to the standard early stages of asthma treatment (including: oxygen therapy, nebulized bronchodilator, Atrovent, injectable corticosteroids) treated with standard asthma treatment and subcutaneous epinephrine ampoules 1.1000 with dosage CC 0.01. The continuation of the treatment process, such as the intervention group, will be carefully checked and recorded by the hospital resident and relevant specialist at intervals upon entering the hospital and according to the table.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Akbar Children's Hospital

##### **Full name of responsible person**

Seyed Javad Seyedi

##### **Street address**

Blvd- Kaveh 14

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9177897157

##### **Phone**

+98 910 171 6090

**Email**  
ghasemim12@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Majid Ghayour-Mobarhan  
**Street address**  
University Street - next to Hoizeh Cinema - Qurashi  
Building - Research and Technology Vice-Chancellor  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177897157  
**Phone**  
+98 910 171 6090  
**Email**  
Mobinmdl94@gmail.com

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Javad Seyedi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Akbar hospital, Kaveh-14 blvd.  
**City**  
Mashhad  
**Province**

Razavi Khorasan

**Postal code**  
9177897157

**Phone**  
+98 910 171 6090

**Email**  
mobinmdl94@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Javad Seyedi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Akbar hospital, Kaveh-14 blvd.  
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Mashhad  
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Razavi Khorasan  
**Postal code**  
9177897157  
**Phone**  
+98 910 171 6090  
**Email**  
mobinmdl94@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Seyed Javad Seyedi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Akbar hospital, Kaveh-14 blvd.  
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Mashhad  
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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

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

Yes - There is a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Yes - There is 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

After the end of the research, the data obtained from the

results and the main consequence or consequences after de-identification can be published.

### When the data will become available and for how long

The start of the access period 6 to 8 months after the end of the study

### To whom data/document is available

All the people who conduct treatment and intervention in the field of research or policy making can use the data of this research.

### Under which criteria data/document could be used

Approval or obtaining permission from legal centers or responsible for research

### From where data/document is obtainable

Applicants can contact the email of the corresponding author of the research.

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

The applicant's response will be reviewed as soon as possible. This time lasts about a week.

### Comments