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

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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

Mashahd

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
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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
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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
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Person responsible for updating data

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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