

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of magnesium sulfate nebulizer and ipratropium bromide in children with asthma attacks admitted to Masih Deneshvari Hospital in Tehran in 1402

Protocol summary

Study aim

of the effectiveness of magnesium sulfate nebulizer and ipratropium bromide in children with asthma attacks admitted to Masih Deneshvari Hospital in Tehran in 1402

Design

Two parallel groups of a blind strain, phase 3, non-randomized on 50 patients, in which 25 patients are prescribed magnesium sulfate nebulizer and 25 patients are prescribed ipratropium bromide nebulizer.

Settings and conduct

Patients with asthma attacks in Masih Deneshvari Hospital in Tehran after receiving three doses of salbutamol nebulizer and no improvement, for 25 patients magnesium sulfate (magnesium sulfate 50%, 0.3 ml (150 mg) diluted with 2.2 ml of distilled water) and ipratropium bromide nebulizer is prescribed for other 25 patients. The respiratory rate and heart rate and pulse oximetry in the intervals before administration and 30, 60 and 120 minutes after receiving the drug will be recorded, and the patients are also examined in these intervals in terms of the presence of wheezing in lung auscultation. If necessary, for each of the patients, if there is no improvement, further treatments and measures will be performed. Patients do not know which type of drug they received because the form and form of both drugs are the same and the study is blinded.

Participants/Inclusion and exclusion criteria

Among the patients aged 2 to 18 years with an asthma attack who were hospitalized after receiving three doses of salbutamol nebulizer and there was no improvement in stable clinical conditions, they were included in the study. Patients with immunodeficiency and underlying disease are excluded from the study.

Intervention groups

Intervention group 1: magnesium sulfate nebulizer.
Intervention group 2: ipratropium bromide nebulizer.

Main outcome variables

Heart rate; Respiration rate; Oxygen saturation level; wheezing during lung examination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057810N1**

Registration date: **2023-04-08, 1402/01/19**

Registration timing: **prospective**

Last update: **2023-04-08, 1402/01/19**

Update count: **0**

Registration date

2023-04-08, 1402/01/19

Registrant information

Name

Niloofar Esfahanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2269 0913

Email address

n.esfahanian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of magnesium sulfate nebulizer and ipratropium bromide in children with asthma attacks admitted to Masih Deneshvari Hospital in Tehran in 1402

Public title
Comparing the effect of magnesium sulfate nebulizer and ipratropium bromide nebulizer in children with asthma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children with asthma attack Over 2 years to 18 years
 After receiving primary asthma attack treatment (salbutamol) Stable clinical conditions
Exclusion criteria:
 Immunodeficiency Underlying disease

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
After obtaining consent from the patient or parents and obtaining permission from the ethics committee, the procedure is explained to the patients or parents, which includes comparing the effectiveness of magnesium sulfate nebulizer and ipratropium bromide, both of which are approved for the treatment of asthma attacks. Both drugs are in liquid and colorless form, and the patient does not know which drug he has received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
 Tehran Province, Tehran, District 1, Daneshjou Blvd
City
 Tehran
Province
 Tehran
Postal code
 1983969411
Approval date
 2023-03-11, 1401/12/20
Ethics committee reference number
 IR.SBMU.MSP.REC.1401.691

Health conditions studied

1

Description of health condition studied
 Magnesium sulfate nebulizer in asthma attack
ICD-10 code
 J45.51
ICD-10 code description
 Severe persistent asthma with (acute) exacerbation

Primary outcomes

1

Description
 Respiratory rate
Timepoint
 Intervals before administration and 30, 60 and 120 minutes after receiving the drug
Method of measurement
 Lung examination

2

Description
 Heart rate
Timepoint
 Intervals before administration and 30, 60 and 120 minutes after receiving the drug
Method of measurement
 Cardiac examination

3

Description
 Blood oxygen saturation percentage
Timepoint
 Intervals before administration and 30, 60 and 120 minutes after receiving the drug
Method of measurement
 Pulse oximetry device

4

Description

Wheezing

Timepoint

Intervals before administration and 30, 60 and 120 minutes after receiving the drug

Method of measurement

Lung examination with a stethoscope

5

Description

Duration of symptoms (less than or more than 6 hours)

Timepoint

Intervals before administration and 30, 60 and 120 minutes after receiving the drug

Method of measurement

Physical examination

6

Description

Treatments after nebulizer administration

Timepoint

After repeated examinations

Method of measurement

General condition of the patient

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Magnesium sulfate nebulizer (magnesium sulfate 50%, 0.3 mL (150 mg) diluted with 2.2 mL of distilled water)

Category

Treatment - Drugs

2

Description

Second intervention group: Ipratropium bromide nebulizer based on standard dose for age according to GINA 2022 guidelines

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Deneshvari Hospital, Tehran

Full name of responsible person

Niloofar Esfahanian

Street address

Shahid Bahonar St. (Niavaran) - Darabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Building No. 2 - Fifth Floor-, Yemen Street - Shahid Arabi Street -Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloofar Esfahanian

Position

Pediatric Pulmonology Fellowship

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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No. 42, Qeytaryeh 12 Meteri St-Tehran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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