Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effect of saline nebulizer 5% with Ventolin VS saline nebulizer 0.9% in the management of moderate asthma attack

Protocol summary

Study aim
Determining the effect of 5% saline nebulizer with Ventolin compared to 0.9% saline with Ventolin in the treatment of moderate asthma attack in children admitted to the emergency room and pediatric department

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. Randomization will be by random number table, and patient checklist will be coded by letters A and B.

Settings and conduct
In this clinical trial, the effect of 5% saline nebulizer along with Ventolin will be compared with 0.9% saline along with Ventolin in the treatment of asthma attacks with moderate severity in children admitted to the emergency ward and the pediatric department of BuAli Hospital in Sari. Patients and treating physician will be blinded.

Participants/Inclusion and exclusion criteria
Children between 1 and 18 years old with a moderate asthma attack and a history of clinically confirmed asthma symptoms (wheezing, shortness of breath, and cough) will be included in the study, and will be excluded if they have heart disease, pneumonia, or rheumatic disease.

Intervention groups
In the intervention group, a vial of salbutamol (Ventolin, salbutamol sulfate 0.15 mg per kg with a minimum dose of 2.5 mg) in 2.5 mL of 5% hypertonic saline (minimum volume of 5 cc) is prescribed for 20 minutes to 3 doses. For the control group, a vial of salbutamol (Ventolin, salbutamol sulfate 0.15 mg per kg with a minimum dose of 2.5 mg) in 2.5 mL of 0.9% normal saline (minimum volume of 5 cc) is prescribed for 20 minutes up to 3 doses.

Main outcome variables
Main outcome variables include improvement in dyspnea, retraction, SPO2 and consciousness, and normal heart rate and respiration rates.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230930059568N1**
Registration date: **2023-12-26, 1402/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-26, 1402/10/05**
Update count: **0**

Registration date
2023-12-26, 1402/10/05

Registrant information
Name
Abbas Dabbaghzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 3334 2334
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2024-03-19, 1402/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Comparison of the effect of saline nebulizer 5% with Ventolin VS saline nebulizer 0.9% in the management of moderate asthma attack

Public title
Comparison of the effect of saline nebulizer 5% with Ventolin VS saline nebulizer 0.9% in the management of moderate asthma attack

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 1-18 years Moderate asthma attack Having a history of asthma symptoms (wheezing, shortness of breath and cough) that has been clinically confirmed

Exclusion criteria:
Heart disease Pneumonia Rheumatic disease

Age
From **1 year** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 40 patients with moderate asthma who meet the study's inclusion criteria are selected. First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 40 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 20 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 40.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and physicians will be blinded so that none of them will know which group they are in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Vice chancellor for Research, Moallem square, Sari

City
Sari

Province
Mazandaran

Postal code
4815838477

Approval date
2023-09-23, 1402/07/01

Ethics committee reference number
IR.MAZUMS.REC.1402.424

Health conditions studied

1

Description of health condition studied
Moderate Asthma

ICD-10 code
J45.40

ICD-10 code description
Moderate persistent asthma, uncomplicated

Primary outcomes

1

Description
Improvement of Dyspnea

Timepoint
0, 20, 40 and 60 minutes following treatment

Method of measurement
Observation

2

Description
Retraction

Timepoint
0, 20, 40 and 60 minutes following treatment

Method of measurement
Observation

3

Description
SPO2

Timepoint
0, 20, 40 and 60 minutes following treatment

Method of measurement
Pals oxymeter

4

Description
Heart rate
Timepoint
0, 20, 40 and 60 minutes following treatment
Method of measurement
Measuring Heart rate

5

Description
Respiratory rate
Timepoint
0, 20, 40 and 60 minutes following treatment
Method of measurement
Measuring respiratory rate

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, a vial of salbutamol (Ventolin, salbutamol sulfate 0.15 mg per kg with a minimum dose of 2.5 mg) in 2.5 mL of 5% hypertonic saline (minimum volume of 5 cc) is prescribed for 20 minutes to 3 doses.
Category
Treatment - Drugs

2

Description
Control group: For the control group, a vial of salbutamol (Ventolin, salbutamol sulfate 0.15 mg per kg with a minimum dose of 2.5 mg) in 2.5 mL of 0.9% normal saline (minimum volume of 5 cc) is prescribed for 20 minutes up to 3 doses.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali Hospital
Full name of responsible person
Dr. Abbas Dabbaghzadeh
Street address
Bu-Ali Sina Hospital, Pasdaran Boulevard, Sari
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Sari
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Mazandaran
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4815838477
Phone
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dabbaghzadeh@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Pedram Ebrahimnejad
Street address
Vice chancellor for Research, Moallem square, Sari
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Abbas Dabbaghzadeh
Position
Assistant professor of clinical allergy and immunology
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Pediatric Infectious Diseases Research Center, Buali hospital, Pasdaran Boulevard, Sari
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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Abbas Dabbaghzadeh

Position
Assistant professor of clinical allergy and immunology

Latest degree
Subspecialist

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Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Sahar Yousefi

Position
Pediatric Resident

Latest degree
Medical doctor

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Pediatrics

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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
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Part of the data is accessible

When the data will become available and for how long
Starting in March 2025

To whom data/document is available
Everyone

Under which criteria data/document could be used
Systematic review articles

From where data/document is obtainable
Contact Dr. Abbas Dabbaghzadeh: dabbaghzadeh@mazums.ac.ir

What processes are involved for a request to access data/document
After contact, information is sent within a few days

Comments