

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 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)

Phone

+98 11 3334 2334

Email address

dabbaghzadeh@mazums.ac.ir

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

+98 911 351 2452

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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

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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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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
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Pediatric Resident
Latest degree

Medical doctor
Other areas of specialty/work
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