

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of standard dose of Albuterol nebulizer, low dose of Albuterol nebulizer with Ipratropium bromide and Albuterol spray on the QT interval in children with moderate to severe asthma.

Protocol summary

Study aim

Determination of the effect of standard dose of Albuterol nebulizer, low dose of Albuterol nebulizer with Ipratropium bromide and Albuterol spray on the QT interval in children with moderate to severe asthma.

Design

The clinical trial with two groups (intervention and control), pragmatic, one-blind, randomized

Settings and conduct

The aim of this study was to investigate the effect of Albuterol on the QT interval in children with moderate to severe asthma in specialty and postgraduate specialty clinic of Heshamateyeh Hospital in Sabzevar city. In this study, participants will be unaware of how to group. Children are randomly assigned to the 3 intervention groups. The response to treatment is evaluated using Electrocardiography at the beginning of the study (before the intervention) after the end of the third treatment and 4 hours after the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 6 months to 15 years Children with moderate to severe asthma or pulmonary obstructive disorder are more than 6 months old Children whose forced Expiratory Volume in First Second (FEV1) is less than 80%. Exclusion criteria: Children with heart and kidney disease Children who have received Albuterol treatment for less than 30 days. Children who have used Systemic Corticosteroids in the last week.

Intervention groups

First intervention group: Patients use a standard dose of inhaler Albuterol (15 mg/kg, maximal 2.5 mg) twice every 20 minutes to 3 times. Second intervention group: Patients use a combination of low dose Albuterol (0.075 mg/kg, maximal 2.5 mg) and Ipratropium bromide (250 µg) twice every 20 minutes to 3 times. Third intervention group: Patients use an inhaled Albuterol (90 micrograms/kg) twice every 20 minutes to 3 times.

Main outcome variables

QT interval in the electrocardiogram

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041252N5**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-04, 1397/10/14**

Update count: **0**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

Mohammad Sahebkar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-19, 1397/08/28

Expected recruitment end date

2019-01-18, 1397/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of standard dose of Albuterol nebulizer, low dose of Albuterol nebulizer with Ipratropium bromide and Albuterol spray on the QT interval in children with moderate to severe asthma.

Public title
Investigating the effect of standard dose of Albuterol nebulizer, low dose of Albuterol nebulizer with Ipratropium bromide and Albuterol spray on the QT interval in children with moderate to severe asthma.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children aged 6 months to 15 years Children with moderate to severe asthma or pulmonary obstructive disorder are more than 6 months old Children whose forced Expiratory Volume in First Second (FEV1) is less than 80%
Exclusion criteria:
 Children with heart and kidney disease Children who have received Albuterol treatment for less than 30 days. Children who have used Systemic Corticosteroids in the last week

Age
From **6 months** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was conducted based on a permutation block, Accordingly, 27 blocks were allocated to patients, in each block, 3 were from following groups, treatment group A, B, and C. Eventually, after completion of the blocks, group A was treated with a standard dose of Albuterol nebulizer, group B was treated with low dose of Albuterol nebulizer with Ipratropium bromide, and group C was treated with albuterol spray.

Blinding (investigator's opinion)
Single blinded

Blinding description
Each person will be assigned a study code A, B, and C, which will only be known to the researcher of the type of groups. The participants are unaware of the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city

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Province

Razavi Khorasan

Postal code

9617913114

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.MEDSAB.REC.1397.062

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

QT interval in the electrocardiogram

Timepoint

Electrocardiography (ECG) is performed at the beginning of the study (before the intervention), after the end of the third treatment and 4 hours after the treatment.

Method of measurement

Electrocardiography (ECG)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients use a standard dose of inhaler Albuterol (15 mg/kg, maximal 2.5 mg) twice every 20 minutes to 3 times.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients use a combination of low dose Albuterol (0.075 mg/kg, maximal 2.5 mg) and Ipratropium bromide (250 µg) twice every 20 minutes to 3 times.

Category

Treatment - Drugs

3**Description**

Intervention group: Patients use an inhaled Albuterol (90 micrograms/kg) twice every 20 minutes to 3 times.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Heshmatiyeh hospital

Full name of responsible person

Raziyeh Salehabadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Alireza Asadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Latest degree

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

No - There is not 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