

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of adding oral Montelukast to standard treatment in controlling of acute asthma attacks in pediatrics

Protocol summary

Study aim

Determining the effect of adding oral montelukast to standard treatment in controlling asthma attacks in children

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. Blocking was used for randomization.

Settings and conduct

Children with severe asthma attacks referred to Hazrat Masoumeh Hospital in Qom. A double-blind clinical trial, based on the randomized block method. Patients and outcome assessors are not aware of the type of drug allocation of patients.

Participants/Inclusion and exclusion criteria

Children aged 5-13 years with severe acute asthma attack; Lack of parental consent to participate in the study; Children suffering from heart, lung, metabolic diseases; Children under 5 years old and over 13 years old; History of anti-leukotriene use in the last two weeks; Children who need intubation for treatment.

Intervention groups

The case group includes children who, in addition to standard treatment, will also receive oral Montelukast from Airocast to control an acute asthma attack. The control group consists of children who will receive standard treatment plus a placebo provided by Airocast to control asthma attacks.

Main outcome variables

speech status; the position of the patient at the time of the attack; restlessness; number of breaths per minute; use of secondary respiratory muscles; state of consciousness; Lung auscultation during the attack; percentage of oxygen saturation; PEF; heart rate Measure with, PEF; Vital Signs; Pulse oximetry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220508054776N1**

Registration date: **2023-11-07, 1402/08/16**

Registration timing: **prospective**

Last update: **2023-11-07, 1402/08/16**

Update count: **0**

Registration date

2023-11-07, 1402/08/16

Registrant information

Name

seyed salman moosavynejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3162 5224

Email address

salman.moosavy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-29, 1402/12/10

Expected recruitment end date

2024-04-29, 1403/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding oral Montelukast to standard treatment in controlling of acute asthma attacks in pediatrics

Public title

The effect of oral montelukast in controlling acute asthma attacks in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 5-13 years Children with an acute asthma attack

Exclusion criteria:

Parents' lack of consent to participate in the study The child's heart, lung, and metabolic diseases Children under 5 years old and over 13 years old History of anti-leukotriene use in the last two weeks Children who need intubation for treatment

Age

From **5 years** old to **13 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (<https://www.sealedenvelope.com>). Allocation concealment is also guaranteed due to the use of special codes generated by the website

Blinding (investigator's opinion)

Double blinded

Blinding description

The special codes created by the website are assigned to the patients and provided to the therapists, and neither the patient nor the therapist knows whether the oral medication that is given to the patient in addition to the standard treatment is Montelukast or a placebo, both medications. It is produced in tablet form by Airocast.

Placebo

Used

Assignment

Parallel

Other design features

Addition of oral montelukast to the standard treatment of acute asthma attack in children

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

Qom,Iran

City

Qom

Province

Ghoum

Postal code

3713649373

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.MUQ.REC.1401.043

Health conditions studied

1

Description of health condition studied

Acute asthma attack

ICD-10 code

J45.50

ICD-10 code description

Severe persistent asthma

Primary outcomes

1

Description

PEF

Timepoint

PEF measurement on arrival and 6 hours later

Method of measurement

Picoflowmeter device

2

Description

The effect of adding oral montelukast to standard treatment on patient's blood oxygen

Timepoint

Upon arrival and 6 hours later

Method of measurement

with pulse oximeter

Secondary outcomes

1

Description

Effect of adding oral montelukast to standard treatment on vital signs

Timepoint

Upon arrival and 6 hours later

Method of measurement

Examination of the patient by a doctor

2

Description

Effect of adding oral montelukast to standard treatment on respiratory distress

Timepoint

Upon arrival and 6 hours later

Method of measurement

Examination of the patient by a doctor

Intervention groups

1

Description

Case group: Children aged 13-5 years will receive 5 mg of oral memontelocut as a single dose in addition to standard primary treatment.

Category

Treatment - Drugs

2

Description

Control group:2. The control group consists of children who will receive standard treatment along with 5 mg of placebo provided by Airocast company to control asthma attacks..

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Masoumeh Hospital

Full name of responsible person

Seyed Salman Mosavinejad

Street address

Imam Street, Shahid Zainuddin Square, Hazrat Masoumeh Hospital

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salman.moosavi1234@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Rahim Ali

Street address

Hazrat Masoumeh Hospital, Zainuddin Square, Qom.

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Postal code

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Email

salman.moosavi1234@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Seyed Salman Moosavinejad

Position

Medical assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

Seyed Salman Moosavinejad

Position

Medical Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts from September 2024

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

A letter to the Vice-Chancellor of Medical Sciences Research, Qom

From where data/document is obtainable

Seyyed Salman Moosavinejad

What processes are involved for a request to access data/document

One Month

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

Ghoum University of Medical Sciences

Full name of responsible person

Seyed salman Moosavynejad

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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Province

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