Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the Efficacy of oral Montelukast in 5-14 year old children hospitalized with severe exacerbated asthma

Protocol summary

Study aim

Determining the effectiveness of montelukast in children aged 5 to 14 years hospitalized with severe asthma attacks

Design

Controlled clinical trial, with parallel groups, double-blind, randomized, phase 4 on 72 patients. Randomization is performed with ras software.

Settings and conduct

The study will be conducted on children aged 5 to 14 years hospitalized with a severe asthma attack. The design is a randomized, double-blind clinical trial, and patients will be divided into two intervention and control groups. Blinding includes patients and outcome assessors.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 5 to 14 years Admission with a diagnosis of severe asthma attack Patients who had a history of salbutamol use in the past two weeks Diagnosed history of moderate to severe persistent asthma Not taking montelukast Exclusion criteria: Lack of parental consent for study entry Patients who were taking phenytoin, phenobarbital, or rifampicin (due to drug interactions) Presence of any other possible diagnosis mimicking asthma symptoms Presence of a clear contraindication to the administration of montelukast Emergence of serious side effects and drug sensitivity to montelukast

Intervention groups

Patients will be divided into two intervention groups (routine treatment plus montelukast) and control (routine treatment plus placebo). Routine treatment includes oxygen therapy, methylprednisolone, and nebulized Deolin.

Main outcome variables

Primary outcomes: Length of stay; Need for adjuvant therapy. Secondary outcomes: Drug side effects; Response by triggering agent.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251021067707N1**
Registration date: **2025-10-25, 1404/08/03**
Registration timing: **prospective**

Last update: **2025-10-25, 1404/08/03**
Update count: **0**

Registration date

2025-10-25, 1404/08/03

Registrant information

Name

Saeed choupani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4625 4148

Email address

schoopany1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of oral Montelukast in 5-14 year old children hospitalized with severe exacerbated asthma

Public title
Evaluating the Efficacy of oral Montelukast in 5-14 year old children hospitalized with severe exacerbated asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 5 to 14 years old Hospitalized with a diagnosis of severe asthma attack Patients who have used salbutamol in the past two weeks A diagnosed history of moderate to severe persistent asthma Not taking Montelukast
Exclusion criteria:
Parents' lack of consent to participate in the study Patients who are taking phenytoin, phenobarbital, or rifampicin (due to drug interactions) The presence of any other possible diagnoses that mimic asthma symptoms There are clear contraindications for prescribing montelukast. The occurrence of dangerous side effects and drug allergies to montelukast
Age
From **5 years** old to **14 years** old
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two intervention groups using Excel software (36 patients, routine treatment regimen for moderate to severe asthma plus montelukast 5 mg orally/daily) and control (36 patients, routine treatment regimen for moderate to severe asthma plus oral placebo/daily).
Blinding (investigator's opinion)
Double blinded
Blinding description
Study participants will be blinded to the placebo, and the outcome assessor will be blinded to the group they are in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences
Street address
Resalat Boulevard
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Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2025-09-24, 1404/07/02
Ethics committee reference number
IR.UMSU.REC.1404.268

Health conditions studied

1

Description of health condition studied
Severe Exacerbation of Asthma
ICD-10 code
J45.51
ICD-10 code description
Severe Exacerbation of Asthma

Primary outcomes

1

Description
Length of hospital stay
Timepoint
The entire length of hospital stay
Method of measurement
Hospital file

2

Description
The need for adjunctive therapies such as magnesium sulfate
Timepoint
The entire length of hospital stay
Method of measurement
Hospital file

Secondary outcomes

1

Description
The occurrence of drug side effects including headache, nausea, diarrhea, and hives
Timepoint

The entire duration of hospitalization

Method of measurement

Taking a patient history

2

Description

Differences in response to treatment based on the type of triggering agent (infectious or non-infectious)

Timepoint

The entire duration of hospitalization

Method of measurement

Taking a patient history

Intervention groups

1

Description

Intervention group: Routine treatment regimen for moderate to severe asthma plus montelukast 5 mg orally/day

Category

Treatment - Drugs

2

Description

Control group: Control group: Routine moderate to severe asthma treatment regimen plus oral/daily placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Hospital, Urmia

Full name of responsible person

Saeed Choupani

Street address

Kashani Crossroads, Kashani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber gholizadeh

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Saeed Choupani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Position
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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