

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

A randomized Clinical trial to evaluate efficacy of intranasal Montelukast on the outcome of asthma attack in 2-12years old children

Protocol summary

Study aim

evaluate efficacy of intranasal Montelukast on the outcome of asthma attack in 2-12years old children

Design

A community-based, practice-oriented, parallel-group, single-blind, randomized controlled clinical trial

Settings and conduct

The samples were selected as available method at Imam Hossein Hospital of Isfahan. Then, completely randomly and based on the children's national number, using spss software, they were randomly assigned to two intervention and placebo groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children 2 to 12 years old
Hospitalization due to an acute asthma attack with a pulmonary index score between 7 and 11 (moderate attack) and a score greater than 12 (severe attack)
Exclusion Criteria: Simultaneous treatment with systemic corticosteroids or antileukotrienes within 4 weeks before admission Other possible causes for the patient's symptoms such as pneumonia Having a history of chronic lung diseases and anatomical airway problems and congenital heart disease History of taking anticonvulsant and immunosuppressive drugs

Intervention groups

In the intervention group, the intranasal Montelukast drug using Montelukast powder from Aldrich Company, carboxymethyl cellulose as a suspending agent, methylparaben and propylparaben as antimicrobial and antifungal preservatives and phosphate buffer to adjust ph by a pharmaceutical specialist It was prepared clinically in the laboratory of the Faculty of Pharmacy of Isfahan University of Medical Sciences and was given to the patient in the form of a fixed dose intranasal spray in a special package. In the placebo group, the drug package containing all the ingredients of the original formula except Montelukast and in the same packaging was used.

Main outcome variables

The severity of the asthma attack

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053760N2**

Registration date: **2022-12-28, 1401/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-28, 1401/10/07**

Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

Neda Abrishami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized Clinical trial to evaluate efficacy of intranasal Montelukast on the outcome of asthma attack in 2-12years old children

Public title

evaluate efficacy of intranasal Montelukast on the outcome of asthma attack in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 2 to 12 years old Hospitalization due to an acute asthma attack with a pulmonary index score (PIS) between 7 and 11 (moderate attack) or a score greater than 12 (severe attack)

Exclusion criteria:

Simultaneous treatment with systemic corticosteroids or antileukotrienes within 4 weeks before admission Other possible causes for the patient's symptoms such as pneumonia Having a history of chronic lung diseases and anatomical airway problems and congenital heart disease History of taking anticonvulsant and immunosuppressive drugs

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were selected as available from Imam Hossein Hospital of Isfahan. Then, completely randomly and based on the children's national number, using spss software, they were randomly assigned to two intervention and placebo groups. After the child entered the hospital, if the entry and exit criteria were met, the children's national number was registered in the software and by choosing the exact ratio of 50% of the children, they were assigned to two randomized groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Both groups received the standard drug. In the intervention group, in addition to the standard drug, montelukast nasal was used, and in the placebo group, placebo was used in the same amount and the same appearance of the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences , Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.MUI.MED.REC.1401.190

Health conditions studied

1

Description of health condition studied

Severe asthma attack

ICD-10 code

J45.5

ICD-10 code description

Severe persistent asthma

Primary outcomes

1

Description

The severity of the asthma attack

Timepoint

On the first day of hospitalization, every 4 hours and on the following days of hospitalization, once a day, patients based on PIS score (pulmonary index score)

Method of measurement

According to the reference, a moderate attack is defined based on the need for auxiliary oxygen-nebulizer albuterol and systemic glucocorticoid, and a severe attack is defined based on the need for auxiliary oxygen-nebulizer salbutamol and ipratropium-systemic glucocorticoid-magnesium sulfate.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intranasal Montelukast drug using Montelukast powder from Aldrich Company, carboxymethyl cellulose as a suspending agent, methylparaben and propylparaben as antimicrobial and antifungal preservatives and phosphate buffer to adjust pH by a clinical pharmacy specialist in the faculty laboratory. Pharmacy of Isfahan University of Medical Sciences is prepared and given to the patient in a special package as a spray with a fixed dose inside the nose. The drug is used once a day.

Category

Treatment - Drugs

2

Description

Control group: The combination of carboxymethyl cellulose as a suspending agent, methyl paraben and propyl paraben as an antimicrobial and antifungal preservative and a phosphate buffer to adjust pH was prepared by a clinical pharmacy specialist in the laboratory of the Faculty of Pharmacy of Isfahan University of Medical Sciences and packaged in a special spray form. It is given to the patient with a fixed intranasal dose. The drug is used once a day.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr. Morteza Sadi Nejad

Street address

Imam Khomeini street

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Isfahan

Province

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3759153111

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

Street address

Vice Chancellor for Research and Technology,
Building No. 4, Isfahan University of Medical Sciences
and Health Services, Hezar Jerib St.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Morteza Sadi Nejad

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person

Neda Abrishami

Position

Student

Latest degree

Master

Other areas of specialty/work

Biostatistics

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Person responsible for updating data

Contact

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Position

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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

Information and data will be available to applicants one
year after obtaining the results.

**When the data will become available and for how
long**

Information and data will be available to applicants one
year after obtaining the results.

To whom data/document is available

Doctors

Under which criteria data/document could be used

Comparison of new drug combination with another new
drug

From where data/document is obtainable

Send a message to dean@med.mui.ac.ir

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

Send a message to dean@med.mui.ac.ir

Comments