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

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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
Isfehan

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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3759153111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

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
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

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Position
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Person responsible for updating data

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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