Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Investigating the effect of early montelukast use on the need for hospitalization, duration of hospitalization and clinical symptoms in children aged 2 to 15 years with the diagnosis of Hyperreactiv Airway Disease (HRAD)

Protocol summary

Study aim
Determining the effect of early use of Montelukast on the need for hospitalization, duration of hospitalization and clinical symptoms in children aged 2 to 15 years with the diagnosis of airway hyperreactivity

Design
A clinical trial with a control group, with a parallel group, a blind strain, randomized, phase 3 on 100 patients (two groups with 50 samples). Simple randomization method is used for randomization.

Settings and conduct
This research is a one-sided blind clinical study with random sampling on children aged 2 to 15 with HRAD referring to Asthma and Allergy Clinic of Imam Ali Clinic and selected patients admitted to the Pediatric Department of Hajar Shahrekord Hospital in 1402. . The intervention group will receive standard treatment in addition to Montelukast and the control group will receive standard treatment. Standard treatment includes salbutamol and cetirizine. Then the clinical symptoms, the need for hospitalization and the length of hospitalization of the two groups will be compared.

Participants/Inclusion and exclusion criteria
Occurrence of clinical symptoms of HRAD and its clinical diagnosis by ;pediatric allergy specialist; Age 2 to 15 years; Other diagnoses, such as pneumonia, are not mentioned or ruled out; The patient does not have known asthma;

Intervention groups
The intervention group (including 50 children aged 2 to 15 with HRAD with random selection) receiving standard treatment plus montelukast (airokast 5 mg chewable brand from Abidi Pharmaceutical Company) and the control group (including 50 children aged 2 to 15 with HRAD randomly selected) receiving standard treatment. Standard treatment includes a short-acting beta-agonist (salbutamol) and an antihistamin (cetirizin).

Main outcome variables
Cough frequency; Cough severity; Pulmonary wheeze; Nocturnal sleep disorder; Arterial oxygen saturation; Need to be hospitalized; Length of hospitalization;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230930059560N1**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

Name
Sadegh Khalilian Shalamzari

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
2024-01-21, 1402/11/01

Expected recruitment end date
2025-01-20, 1403/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of early montelukast use on the need for hospitalization, duration of hospitalization and clinical symptoms in children aged 2 to 15 years with the diagnosis of Hyperreactiv Airway Disease (HRAD)

Public title
Investigating the effect of early montelukast use on the need for hospitalization, duration of hospitalization and clinical symptoms in children aged 2 to 15 years with the diagnosis of Hyperreactiv Airway Disease (HRAD)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with airway hyperreactivity between 2 years and 15 years who have not recently used systemic or inhaled corticosteroids and are not known to have asthma. Absence of serious diseases that interfere with the research results (such as severe heart or lung diseases). Has not recently used long-term bronchodilators or theophylline.
Exclusion criteria:
patient with known asthma Other diagnoses such as pneumonia are relevant Recent treatment with systemic or inhaled corticosteroids
Age
From **2 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The research samples are divided into the test group and the control group by simple randomization (in this way, based on the patient's arrival time, we prepare the list of patients and consider the even numbers as the test group and the odd numbers as the control group) .
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to blind the study, the data collector, clinical care provider and data analyst will be unaware of whether the patients received montelukast or not.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences
Street address
Parastar Ave, Shahrekord Hajar Hospital
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Approval date
2023-10-16, 1402/07/24
Ethics committee reference number
IR.SKUMS.MED.REC.1402.054

Health conditions studied

1

Description of health condition studied
Hyperreactiv airway disease
ICD-10 code
J70.9
ICD-10 code description
Respiratory conditions due to unspecified external agent

Primary outcomes

1

Description
Need to be hospitalized
Timepoint
At the beginning of the study and then every 3 days until the end of 2 weeks
Method of measurement
Clinical examination: pulmonary auscultation with a stethoscope, measurement of arterial oxygen with a pulse oximeter

2

Description
Duration of hospitalization
Timepoint
From the time of admission to the hospital until

discharge on a daily basis

Method of measurement

Counting the number of days of hospitalization

Secondary outcomes

1

Description

Cough severity

Timepoint

At the beginning of the study and then every 3 days until the end of 2 weeks

Method of measurement

Based on the scoring system of a standardized 5-question questionnaire

2

Description

Cough frequency

Timepoint

At the beginning of the study and then every 3 days until the end of 2 weeks

Method of measurement

Based on the scoring system of a standardized 5-question questionnaire

3

Description

Nocturnal sleep disorder

Timepoint

At the beginning of the study and then every 3 days until the end of 2 weeks

Method of measurement

Based on the scoring system of a standardized 5-question questionnaire

4

Description

Pulmonary wheezing

Timepoint

At the beginning of the study and then every 3 days until the end of 2 weeks

Method of measurement

Clinical examination: pulmonary auscultation with a stethoscope

5

Description

Arterial oxygen saturation

Timepoint

at the beginning of the research and then every 3 days until the end of 2 weeks

Method of measurement

Clinical examination: measurement of arterial oxygen with a pulse oximeter

Intervention groups

1

Description

Intervention group: including 50 children aged 2 to 15 years with HRAD diagnosis receiving standard treatment (including short-acting beta-agonist spray (salbutamol) and antihistamine (cetirizine)) plus Montelukast (Airokast 5 mg chewable brand from Abidi Pharmaceutical Company)

Category

Treatment - Drugs

2

Description

Control group: including 50 children aged 2 to 15 with HRAD diagnosis receiving standard treatment (including short-acting beta-agonist spray (salbutamol), antihistamine (cetirizine))

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord's specialized and super-specialized Imam Ali clinic

Full name of responsible person

Mohammad Ali Zamani

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2

Recruitment center

Name of recruitment center

Hajar Shahrekord educational-therapeutic center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord 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
Shahre-kord 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
Shahre-kord University of Medical Sciences
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Position
Pediatric assistant
Latest degree
Medical doctor
Other areas of specialty/work
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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

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Except for personal information about people, all of our data will be shared if certain requirements are met. Our data will only be used for comparable study and peer review by other researchers. Anyone working in universities or scientific institutions who wants to do similar study or confirm the accuracy of our data can access our data.

From where data/document is obtainable

All qualified individuals can collect data by referring to the project manager in order to acquire information. Contact information is available via email at st-khalilian@skums.ac.ir or the contact number 00989137210665

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments