

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of montelukast compared with inhaled steroids on clinical symptoms in children with asthma in 2017

Protocol summary

Summary

Objectives: The study aimed to determine the effect of montelukast on clinical symptoms of children with asthma compared with inhaled steroids **Design:** In this randomized double-blind clinical trial, after explaining the study and obtaining informed consent from patients, 100 eligible subjects were selected through convenience sampling and then fell into intervention group (a) and active control group (B) by randomized block design. The block size will be considered to be 4. Group A will receive conventional drug (inhaled steroids). Group B will receive montelukast. **Methodology:** Every treatment period takes 3 months. The dosage of montelukast is one capsule daily in healthy subjects. A questionnaire consisted of two parts is used to collect data. The first part is related to demographic characteristics (gender, age, education level, etc.) and the second part is related to the patient's condition and clinical symptoms which are collected using standard questionnaires VAS and ChildACT. This questionnaire will be filled in at zero time, at the end of the first month, at the end of the second month and at the end of the third month (actually, the answers to the questionnaire VAS as scoring from 0 to 10 will be weekly provided). Asthma severity and the control of asthma symptoms will be assessed according to GINA recommendations. Participants included children of 4-11 years old with asthma according to GINA criterion **Interventions:** giving montelukast to the patients **Main consequences:** patients' clinical symptoms

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050723046N3**

Registration date: **2017-05-31, 1396/03/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Mehdi Gholamzadeh Baeis

Name of organization / entity

Qom Branch Of Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 61 3391 8586

Email address

dr.m.gholamzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Qom Branch Of Islamic Azad University

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of montelukast compared with inhaled steroids on clinical symptoms in children with asthma in 2017

Public title

The effect of montelukast compared with inhaled steroids on clinical symptoms in children with asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 4-11 years old; having asthma (according to GINA criterion); patients with mild persistent asthma (according to GINA criterion).

Exclusion criteria: any medical disease that affects the study results, such as Bacterial or Viral Infections of the Respiratory Tract and uncontrolled asthma (peak expiratory flow < 20%); taking antibiotics during the month before entering the study; non-compliance of taking drug: the participants' compliance will be determined from the number of montelukasts not taken at the end of each month (montelukast has been taken for more than 24 days per month).

Age

From **4 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom branch of Islamic Azad University

Street address

School of Medicine, Islamic Azad University, 15 Khordad street, Qom

City

Qom

Postal code

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

IR.IAU.Qom.REC.1395.37

Health conditions studied

1

Description of health condition studied

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes

1

Description

Clinical signs asthma (cough, wheezing, dyspnea)

Timepoint

before intervention, the end of the first month, the end of second month, the end of the third month

Method of measurement

According to GINA questionnaire and Child ACT

Secondary outcomes

1

Description

Severe of Asthma

Timepoint

Before intervention, the end of the first month, the end of second month, the end of the third month

Method of measurement

According to need for treatment as recommended by GINA

Intervention groups

1

Description

The intervention group: Take the medication montelukast to patients. Each treatment period of 3 months. Drug dosage is one capsule daily.

Category

Treatment - Drugs

2

Description

Control group: an inhaled steroid drugs to patients. Each treatment period of 3 months. Two puffs daily drug dosage

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gulpaigani Hospital

Full name of responsible person

Mehdi Gholamzadeh Baeis

Street address

Hospital Gulpaigani, Motahari Square

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Of Qom Branch Of Islamic Azad University

Full name of responsible person

Dr Mohammad Javad Qasemzadeh

Street address

School of Medicine, Islamic Azad University, 15 Khordad street, Qom

City

Qom

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Of Qom Branch Of Islamic Azad University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qom Branch Of Islamic Azad University

Full name of responsible person

Mehdi Gholamzadeh Baeis

Position

Student Of M.D

Other areas of specialty/work

Street address

School of Medicine, Islamic Azad University, 15 Khordad street, Qom

City

Qom

Postal code

Phone

+98 25 3280 8080

Fax

Email

Dr.M.Gholamzadeh@Gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qom Branch Of Islamic Azad University

Full name of responsible person

Dr Mohammad Javad Qasemzadeh

Position

Pediatrician

Other areas of specialty/work

Street address

School of Medicine, Islamic Azad University, 15 Khordad street, Qom

City

Qom

Postal code

Phone

+98 25 3280 8080

Fax

Email

Qasemzade.M@Gmail.Com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qom Branch Of Islamic Azad University

Full name of responsible person

Mehdi Gholamzadeh Baeis

Position

Student Of M.D

Other areas of specialty/work

Street address

School of Medicine, Islamic Azad University, 15 Khordad street, Qom

City

Qom

Postal code

Phone

+98 25 3280 8080

Fax

Email

Dr.M.Gholamzadeh@Gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty