

# 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*