

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation efficacy of montelukast in children gastroenteritis

#### Protocol summary

##### Study aim

Evaluation efficacy of montelukast in children gastroenteritis

##### Design

Clinical trial with control group and open label treatment on 60 patients

##### Settings and conduct

This study will be performed on 60 patients with diarrhea at Amirkola Children's Hospital- Babol. This study is open label. All patients in the control group receive standard treatment includes serum therapy and zinc sulfate syrup. In the treatment group, in addition to the standard treatment of Montelukast, it is prescribed at a dose of 5 mg once a day for 14 days. Before and at the end of the study, blood samples are taken from patients and serum is isolated. In the serum sample, the amount of interleukin-13 is measured with an ELISA kit. Clinical signs of diarrhea, number of times per day and abdominal pain will be recorded before and during treatment and at the end.

##### Participants/Inclusion and exclusion criteria

1. All patients with gastroenteritis, at any age 2 to 12 years and of both sexes, boys and girls are included in the study. 2. Patients with incurable disease or dangerous disease other than gastroenteritis. 3. Satisfaction of patients or their trustees (informed consent will be obtained from patients or patient trustees to participate in the study.)

##### Intervention groups

The control group is the group that receives routine treatment. In addition to routine treatment, the treatment group also receives Montelukast.

##### Main outcome variables

Frequent diarrhea Abdominal pain

#### General information

##### Reason for update

##### Acronym

MGE

##### IRCT registration information

IRCT registration number: **IRCT20180624040213N3**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

##### Registration date

2022-02-01, 1400/11/12

##### Registrant information

###### Name

Hossein Najafzadehvarzi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3247 6421

###### Email address

h.najafzadeh@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-11, 1400/09/20

##### Expected recruitment end date

2022-07-22, 1401/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation efficacy of montelukast in children gastroenteritis

##### Public title

Effect of montelukast in treatment of gastroenteritis

##### Purpose

Health service research

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

1. All patients with gastroenteritis, at any age 2 to 12 years and of both sexes, boys and girls are included in the study. 2. Patients with incurable disease or dangerous disease other than gastroenteritis. 3. Satisfaction of patients or their trustees (informed consent will be obtained from patients or patient trustees to participate in the study.)

### **Exclusion criteria:**

Patients who develop a disease other than gastroenteritis during the study or find drug allergies Refrain from collaborating with the research team during the study or refrain from taking medication and clinical examinations according to the study method.

## **Age**

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

## **Gender**

Both

## **Phase**

1

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **60**

## **Randomization (investigator's opinion)**

Not randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Not 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 Islamic Azad University,  
Ayatollah Amoli Branch

##### **Street address**

Mazandaran Babol Ayatollah Khamenei St. Ershad 15

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

4719765574

#### **Approval date**

2021-08-24, 1400/06/02

#### **Ethics committee reference number**

IR.IAU.AMOL.REC.1400.035

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Diarrhea

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Measurement of serum interleukin level 13

#### **Timepoint**

Measurement of serum interleukin level 13 at the beginning of the study and 14 days after consumption of Montelukast

#### **Method of measurement**

Analysis of covariance (ANCOVA) will be used to evaluate the effect of montelukast on IL13 (before and after treatment) in both groups.

## **Secondary outcomes**

### 1

#### **Description**

Frequency of diarrhea and abdominal pain in the study of the effectiveness of Montelukast in the treatment of pediatric gastroenteritis

#### **Timepoint**

Evaluation of abdominal pain and frequency of diarrhea and measurement of serum level of interleukin 13 at the beginning of the study and 14 days after taking Montelukast

#### **Method of measurement**

How to measure the frequency of diarrhea excretion according to Bristol criteria, Evaluation of abdominal pain based on criteria Visual Analogue

## **Intervention groups**

### 1

#### **Description**

Control group: All patients in the control group receive standard gastroenteritis treatment. Routine treatment of gastroenteritis includes serum therapy and zinc sulfate syrup). Receive routine treatment (ORS and zinc) for 14 days.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: In addition to routine treatment (ORS and zinc), they receive Montelukast for 14 days. in the treatment group, Montelukast, is prescribed at a dose of

5 mg once a day for 14 days.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Amirkola Children's Hospital, Darolshafa Street,  
Amirkola, Babol, Mazandaran,

**Full name of responsible person**

Mohammad Saeed Poulae

**Street address**

Ershad Alley 15, Ayatollah Khamenei St, Babol,  
Mazandaran

**City**

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**Province**

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**Postal code**

4719765574

**Phone**

+98 11 3227 1497

**Email**

mstpoulae@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

**Street address**

Babol university of medical sciences, Ganjafrooz  
street, Kargar squer, Babol

**City**

Babol

**Province**

Mazandaran

**Postal code**

4774547176

**Phone**

+98 11 3219 9936

**Email**

rezaghadimi@yahoo.com

**Web page address**

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Babol University of Medical Sciences

**Proportion provided by this source**

30

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Hossein Najafzadehvarzi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Medical faculty, Babol University of Medical Sciences,  
Ganjafrooz street, Kargar squer, Babol

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Hossein Najafzadehvarzi

**Position**

Professor

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Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Hossein Najafzadehvarzi

**Position**

Professor

**Latest degree**

Ph.D.

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Babol

**Province**

Mazandaran

**Postal code**

4719765574

**Phone**

+98 11 3247 6421

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available