

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

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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

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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,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hossein Najafzadehvarzi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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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