

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of the probiotic effect of *Lactobacillus ruteri* in the intestinal preparation regimen of children undergoing colonoscopy

Protocol summary

Study aim

Determination of probiotic effect of *Lactobacillus ruteri* in intestinal preparation regimen of colonoscopic candidate children referred to Tehran Pediatric Medical Center Hospital

Design

This study is a double-blind study with a control group with parallel randomized groups and is performed on 80 patients in phase 3.

Settings and conduct

This study will be performed on 80 children and adolescents aged 2-14 years in the Children's Medical Center Hospital. The study will be conducted in double-blind with the control group. The intervention group will receive a probiotic supplement with pedrolax and bisacodyl powder and the control group will receive a placebo with pedrolax and bisacodyl powder for 10 days. At the beginning and after 10 days, the different effects of the intervention on these people are examined and compared.

Participants/Inclusion and exclusion criteria

Children in the age range of 2 to 14 years, No history of any allergic reactions, No inflammatory bowel disease including Crohn's disease and ulcerative colitis, no intestinal obstruction, no megacolon toxin and no severe constipation.

Intervention groups

A group of patients will undergo bisacodyl and polyethylene glycol diet 48 hours before colonoscopy. The other group will undergo the *Lactobacillus ruteri* probiotic diet ten days before the colonoscopy and the bisacodyl and polyethylene glycol diet 48 hours before the colonoscopy.

Main outcome variables

Boston Bowel Preparation Scale, Duration of colonoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220413054526N1**
Registration date: **2022-06-02, 1401/03/12**
Registration timing: **prospective**

Last update: **2022-06-02, 1401/03/12**

Update count: **0**

Registration date

2022-06-02, 1401/03/12

Registrant information

Name

Parisa Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2014

Email address

parisarahmani59@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the probiotic effect of *Lactobacillus ruteri* in the intestinal preparation regimen of children undergoing colonoscopy

Public title

Evaluation of the probiotic effect of Lactobacillus ruteri in the intestinal preparation regimen of children undergoing colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children in the age range of 2 to 14 years. No history of any allergic reactions. No inflammatory bowel disease including Crohn's disease and ulcerative colitis, no intestinal obstruction, no megacolon toxin and no severe constipation.

Exclusion criteria:

Having any acute illness The occurrence of any accident that affects a person's health. Acceptance rate less than 80% Changes in medications taken during the study period Exclusion based on personal preference of participants or their parents

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used as Stratified Randomization using the Permuted block randomization method with quadruple and double blocks. According to the sample size of 80 that has been determined, the quadruple and double blocks will be produced using the online site (www.sealedenvelope.com). In the Stratified Randomization method, age and BMI will be used as layers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. Participants will be divided into 2 groups receiving Lactobacillus ruteri probiotic with Pedrolax powder and Bisacodyl and the placebo receiving group with Pedrolax powder and Bisacodyl. Due to the double-blindness of the study, before starting the study, sets of cans containing probiotic supplementation will be prepared by someone other than the researcher, and the placebo will be similar in appearance to probiotic supplementation, so that the researcher does not know the type of treatment received by each group. In addition, the researcher in the evaluation phase of the desired outcomes from the allocation of participants in each of the groups (intervention and control group) until after the end of the intervention period will be uninformed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Children's Medical Center- Tehran University of Medical Sciences

Street address

Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2022-05-19, 1401/02/29

Ethics committee reference number

IR.TUMS.CHMC.REC.1401.047

Health conditions studied**1****Description of health condition studied**

Eosinophilic gastritis or gastroenteritis

ICD-10 code

K52.81

ICD-10 code description

Eosinophilic gastritis or gastroenteritis

Primary outcomes**1****Description**

Boston Bowel Preparation Scale

Timepoint

End of the study

Method of measurement

Questionnaire

2**Description**

Duration of colonoscopy

Timepoint

End of the study

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Age

Timepoint

End of study

Method of measurement

Questionnaire

2

Description

Sex

Timepoint

End of study

Method of measurement

Questionnaire

3

Description

Weight

Timepoint

Beginning and end of the study

Method of measurement

scale

Intervention groups

1

Description

Intervention group: Ten days before the colonoscopy, Pediatrics will be on the Lactobacillus ruteri probiotic diet, and 48 hours before the colonoscopy, they will be on the bisacodyl and polyethylene glycol diet. The protocol for using the probiotic Lactobacillus ruteri is to dissolve the rotroflora sachet 10 sachets daily for children 2 to 5 years old and two sachets daily for children 5 to 14 years old in water, yogurt or lukewarm food 10 days before colonoscopy. It is also recommended that all patients use a well-drained fluid diet 48 hours before colonoscopy.

Category

Treatment - Other

2

Description

Control group: Pediatrics will receive a placebo supplement ten days before the colonoscopy and will also be on a bisacodyl and polyethylene glycol diet 48 hours before the colonoscopy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Parisa Rahmani

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Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

اکبر فتوحی، معاون تحقیقات و فناوری، دانشگاه علوم پزشکی تهران.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parisa Rahmani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

-