Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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)

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+98 21 6147 2014

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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 of80 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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Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran
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Person responsible for updating data

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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
-