

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of colonoscopy preparation and probiotic consumption on the severity of functional constipation of the gastrointestinal tract (functional constipation and irritable bowel syndrome with constipation pattern)

Protocol summary

Study aim

The effect of colonoscopy preparation and probiotic consumption on the severity of functional constipation of the gastrointestinal tract (functional constipation and irritable bowel syndrome with constipation pattern)

Design

Non-randomized Clinical trial with control group with parallel groups, phase 2-3 on 74 patients

Settings and conduct

This study will be performed in Khorshid Hospital in Isfahan and patients with functional constipation will be admitted. In the intervention group, in addition to receiving peg powder after colonoscopy, they will receive probiotic capsules and in the control group, they will receive placebo capsules. The severity of constipation before and after interventions will be measured and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria Having functional constipation according to Roman criteria 4, having irritable bowel syndrome with constipation pattern according to Roman criteria, freely and consciously written consent to participate in the study, age over 18 years
Exclusion criteria Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract, any serious physical problems or illnesses such as inflammation or malignancy, any physical problems that prevent you from doing physical activity, addiction to drugs or sleeping pills, history of chronic diseases such as diabetes

Intervention groups

Intervention group: patients will receive PEG powder pre-colonoscopy. Also, these patients will receive two bio-flora capsules (lactic acid bacteria) for 8 weeks a day (after breakfast and after dinner) and the severity of constipation will be measured. **Control group:** patients

will receive PEG powder pre-colonoscopy. Also, these patients will receive two placebo capsules and the severity of constipation will be measured during and after the interventions.

Main outcome variables

Constipation score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210817052219N1**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **prospective**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

Registration date

2021-10-13, 1400/07/21

Registrant information

Name

Leila Khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3663 7626

Email address

leila.kh7501256@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-20, 1400/08/29
Expected recruitment end date
 2022-12-20, 1401/09/29
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty
Scientific title
 The effect of colonoscopy preparation and probiotic consumption on the severity of functional constipation of the gastrointestinal tract (functional constipation and irritable bowel syndrome with constipation pattern)
Public title
 Colonoscopy preparation and probiotic use on the severity of constipation
Purpose
 Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
 Having functional constipation in people over 18 years according to ROME IV criteria Having irritable bowel syndrome with constipation pattern according to ROME IV criteria Free and informed written consent to participate in the study Age over 18 years
Exclusion criteria:
 Any history of chronic inflammatory disease or structural disease of the gastrointestinal tract Any serious physical problems or illnesses such as inflammation or malignancy Any physical problems that prevent you from doing physical activity Addiction to drugs or sleeping pills History of chronic diseases such as diabetes
Age
 From **18 years** old
Gender
 Both
Phase
 2-3
Groups that have been masked
No information
Sample size
 Target sample size: **74**
Randomization (investigator's opinion)
 Not randomized
Randomization description
Blinding (investigator's opinion)
 Not blinded
Blinding description
Placebo
 Used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.MUI.MED.REC.1400.170

Health conditions studied

1

Description of health condition studied

Functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Constipation score

Timepoint

Before receiving the colonoscopy preparation and then in weeks 2, 4, 8 after the start of the intervention and 4 weeks after the end of the intervention (week 12)

Method of measurement

ROM 3 criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients will receive PEG powder before colonoscopy. After colonoscopy, patients receive two bio-flora (lactic acid bacteria) capsules from Tak Gene for 8 weeks a day (after breakfast and after dinner) and will measure the severity of constipation during and after the interventions.

Category

2**Description**

Control group: In this group, patients will receive PEG powder before colonoscopy. Also, these patients will receive two placebo capsules containing starch per day for 8 weeks (after breakfast and after dinner) and the severity of constipation will be measured during and after the interventions.

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Isfahan Khorshid Hospital

Full name of responsible person

Amir Hosseini

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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8169311478

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

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haghjoo.sh@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Soheilipour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments