Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of probiotics in preventing lower rectal resection syndrome in patients with rectal cancer who have undergone lower anterior rectal resection

Protocol summary

Study aim
Determining the effectiveness of probiotics in relieving the symptoms of lower rectal resection syndrome
Design
A Double-blind Randomized, placebo-controlled clinical trial will perform on 180 patients. To randomize, we will use a sequence of random numbers using SPSS.
Settings and conduct
This study is a clinical trial that is performed in Sina Hospital on patients who have undergone low anterior surgery and have an ileostomy. Patients are randomly divided into 2 groups of 90.
Participants/Inclusion and exclusion criteria
1- Age 18-57 years 2- Proven adenocarcinoma 3- With anterior resection indication, 4- Ability to fill out a questionnaire 5- Rectal cancers who underwent radiotherapy.
Intervention groups
The target groups include patients with rectal cancer who underwent anterior rectal resection and have an ileostomy. The intervention group will be patients who receive probiotics after surgery and the control group will be patients who will receive placebo.
Main outcome variables
Incidence of complications in patients, Duration of hospitalization, The duration of the novel having an ostomy, Death, Surgical method, The interval between surgery time and ileostomy closure, Total score, Symptoms score, Emotional score, Physical function score, Social function score, Medical treatment score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210704051784N1**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **prospective**

Last update: **2021-10-26, 1400/08/04**
Update count: **0**
Registration date
2021-10-26, 1400/08/04

Registrant information
Name
Nima Afsharipur
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-21, 1400/08/30
Expected recruitment end date
2022-07-20, 1401/04/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of probiotics in preventing lower rectal resection syndrome in patients with rectal cancer who have undergone lower anterior rectal resection

Public title

Evaluation of the effect of probiotics in preventing low anterior resection syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 57 years Indicated removal of the anterior part of the lower rectum Confirmed adenocarcinoma Ability to fill out a questionnaire Patients with Rectal cancers whom undergone radiotherapy

Exclusion criteria:

Use antibiotics or probiotics a week before Systemic evidence of obstruction in preoperative endoscopy Urinary and fecal incontinence Metastatic cancer Advanced cardiovascular and cerebral disease Pregnant and lactating mothers Irritable Bowel Syndrome History of chemotherapy or radiotherapy Symptoms of infection or immunodeficiency disease Abnormal creatinine Abnormal liver enzymes Uncontrolled hypertension or diabetes Patients with celiac disease or probiotic intolerance

Age

From **18 years** old to **57 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who go under low anterior surgery and have ileostomy will randomly divided into 2 groups of 90. First, the patients will be explained how to do the job and 90 patients will be given probiotic pills daily and the other group will be given a placebo as a control group. Patients will be treated for 4 weeks. Block randomization method with a block size of 4 (marked with two As and two Bs randomly) will be used to randomize patients and assign them into two groups. Each A or B will be assigned to the specific number in the random number table. Only the treatment producing team including the specialist in pharmacology and the operator will be aware of the contents of each bottle (probiotic or placebo). The nursing team will attach the label of the bottles containing the random numbers. An experienced clinician will be responsible for doing the randomization in our study who generated the random allocation sequence and enrolled participants. Also, He/she will be responsible for the assignment of the participants to the intervention group. He/she will not have any role in participants' treatment, analyzing the data, and writing the article of this trial and she is only responsible for blinding the study.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, corner of Quds

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1400.041

Health conditions studied

1

Description of health condition studied

Patients with rectal cancer whose adenocarcinoma is pathologically proven and indicated for anterior resection.

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description

Level of Quality of Life

Timepoint

The questionnaire will be completed by the patients of both groups once before starting the drug treatment and after that by the patient every week.

Method of measurement

The Gastrointestinal Quality of Life Questionnaire consists of 36 different items that include general and specific symptoms, physical and mental functioning, and social dysfunction related to gastrointestinal diseases. Each item has a score from 0 to 4. The score of this questionnaire is from 0 to 144, of which 0 is the worst

possible case and 144 is the best possible case. The Anterior Resect Syndrome Questionnaire examines 5 important questions, including 1. Incontinence for stool 2. Incontinence for liquid stool 3. Frequency 4. Clustering 5. Urgency. The score of this questionnaire is from 0 to 42, according to which if the patient scores 0 to 20, he does not have anterior resection syndrome. A score of 21 to 29 indicates a mild form of the syndrome, and a score of 30 to 42 indicates a severe form.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Multilateral probiotics in the form of LactoCare capsules made by Zist-Takhmir Company will be given to patients every 12 hours (after lunch and after dinner) for 4 weeks. Participants will be given the necessary training before conducting this research.
Category
Treatment - Drugs

2

Description
Control group: Patients will be given 2 gr of powder (350 mg of xylooligosaccharides and 36 mg of fructooliosacaride as prebiotics without probiotic strain twice a day for 4 weeks. This product has been also made by Zist-Takhmir company. Participants will be given the necessary training before conducting this research.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Nima Afshari
Street address
Emam Khomeini Avenue
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nima Afshari pour
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Email
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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
Nima Afshari pour
Position
resident
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Nima Afshari pour

Position

resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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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