Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effects of probiotic supplementation on related side effects after chemotherapy and laboratory symptoms in metastatic gastrointestinal cancer patients:A randomized control trial

Protocol summary

Study aim
Description and comparison of primary and clinical information of patients with metastatic GI cancer between the two case and control groups

Design
The clinical trial of Bayini has a randomized control group without blinding in phase 3 on 160 patients based on the Ralloc package.

Settings and conduct
Due to the fact that the doctor, researchers and the patient know about the type of intervention received, the study is designed as an open label (non-blinding).

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-65 years old with metastatic GI cancer who are undergoing chemotherapy Not having lactose intolerance No symptoms of diarrhea, constipation, nausea and vomiting, mucositis before receiving chemotherapy The operation status is 0 or 1 according to ECOG (Eastern and has Cooperative Oncology Group) Exclusion criteria: unwillingness to participate in the study, History of IBD Previous history of colectomy Use of any antibiotic or other drugs

Intervention groups
Patients who take 500 mg Femilact probiotic capsules from the bio-fermenting company twice a day before breakfast and dinner for one week, which contains casei, lactobacillus lactobacillus acidophilus, lactobacillus rhamnosus, lactobacillus bulgaricus, bifidobacterium breve, bifidobacterium longum, streptococcus thermophiles, and fructooligosaccharides

Main outcome variables
Side effects, including frequency, severity of diarrhea and vomiting, mucositis, constipation after each course of chemotherapy for up to three months, as well as laboratory criteria, including CEA, CA19. 9 and inflammatory factors such as diff, IL 6- ESR, CRP, ferritin, pct, fibrinogen, CBC will be checked before and after receiving probiotics for 3 and 6 months

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240629062278N1**
Registration date: **2024-07-03, 1403/04/13**
Registration timing: **prospective**

Last update: **2024-07-03, 1403/04/13**
Update count: **0**

Registration date
2024-07-03, 1403/04/13

Registrant information
Name
Niusha Nosrati
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 7343 0000
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niushanosrati72@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-05, 1403/04/15
Expected recruitment end date
2024-12-05, 1403/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of probiotic supplementation on related side effects after chemotherapy and laboratory symptoms in metastatic gastrointestinal cancer patients:A randomized control trial

Public title
he Effects of probiotic supplementation on related side effects after chemotherapy laboratory symptoms and in metastatic gastrointestinal cancer

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
65-18 years old with metastatic GI cancer undergoing chemotherapy No lactose intolerance Did not have any symptoms of diarrhea, constipation, nausea, vomiting, or mucositis before receiving chemotherapy, Functional status 0 or 1 according to ECOG (Eastern Cooperative Oncology Group)

Exclusion criteria:
Reluctance of the patient to participate in the study Description of underlying diseases including IBD \History of Colectomy Taking any antibiotic or other drugs

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
All people eligible to enter the study will be randomly assigned to one of the two groups to receive probiotics and placebo with a ratio of 1:1. The randomization method will be block permuted randomization, based on the sample size, the blocks will be divided into 26 blocks of sizes two, four, six, eight, and ten to complete the sample size using the "Ralloc" package in the STATA software. Patients will be included in each group based on the determined sample size and the list of random individuals (along with a special research code for each individual).

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, Faculty of Medicine, Shahid Beheshti University of Medical Science

Street address
Shahid Beheshti University of Medical Science, Arabi Ave, Daneshjoo Blv, Velenjak, Tehran

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2024-06-18, 1403/03/29

Ethics committee reference number
IR.SBMU.MSP.REC.1403.164

Health conditions studied

1

Description of health condition studied
GI Metastatic Cancer

ICD-10 code
Z85

ICD-10 code description
Personal history of malignant neoplasm

Primary outcomes

1

Description
Examination of gastrointestinal symptoms: examination of changes in the severity of symptoms up to three chemotherapy courses (equivalent to 3 months) compared to zero time

Timepoint
Zero time & 3 months later

Method of measurement
The severity of diarrhea is described using the CTCAE Common Terms for Adverse Events criteria (NCI, National Cancer Institute). The severity of mucositis according to the CTCAE criteria.The type and severity of constipation based on the criteria (BRISTOL BSFS)

2

Description
Examining inflammatory factors and tumor markers: Examining the changes three and six months after the intervention compared to zero time

Timepoint

Zero time, 3 and 6 months later

Method of measurement

laboratory evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Take one probiotic capsule (500 mg) containing casei, lactobacillus acidophilus, lactobacillus rhamnosus, lactobacillus bulgaricus, bifidobacterium breve, bifidobacterium longum, streptococcus thermophiles and prebiotic a as fructooligosaccharides before breakfast and dinner twice a day and It is up to one week after starting the treatment.

Category

Treatment - Drugs

2

Description

Control group: Under the title of control group without receiving placebo control (no-treatment)(group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Niusha Nosrati

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Madani Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti University of Medical Science, Arabi Ave, Daneshjoo Blv, Velenjak, Tehran, Iran

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niusha Nosrati

Position

Resident

Latest degree

Medical doctor

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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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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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 patient information will be entered into the database (Excel file) after collecting it in a paper checklist, and after checking the range of data in terms of the presence of outliers and cleaning it (data cleaning), it will be prepared for statistical analysis. The final data file will be provided to the research department of internal diseases department to conduct further studies.
When the data will become available and for how long
6 months after publishing data
To whom data/document is available
Academic Researchers
Under which criteria data/document could be used
If there is a positive conclusion from the research and the need for further studies
From where data/document is obtainable
Dr Niusha Nosrati, Internal Medicine Clinic, Imam Hossein Hospital
What processes are involved for a request to access data/document
Through the written request of the applicant to the research department of the hospital
Comments