

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation the effect of probiotics on gastrointestinal symptoms in patients with gastric cancer

Protocol summary

Study aim

Determining the effect of probiotics on gastrointestinal symptoms in patients with gastric cancer

Design

Clinical trial with control group, with parallel groups, randomized

Settings and conduct

Sixty patients referred to the gastrointestinal clinic of the teaching hospitals of the Islamic Azad University of Mashhad, based on inclusion criteria, will be randomly assigned (blocking) to the intervention or control group without the knowledge in which group they are in. VAS visual scale for Gastrointestinal symptoms such as abdominal pain, diarrhea, constipation and bloating will be completed for both group before and two months after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 70 years, Endoscopically confirmed gastric cancer and pathology that are in the recovery phase (their treatment is over), Refer to the gastroenterology clinic of Azad University of Mashhad Educational hospitals, Informed consent to enter the study. Exclusion criteria: Obvious neurological disease, Probiotic consumption in the past month, Dissatisfaction with inclusion in the study, Lack of cooperation, Lack of proper use of the Probiotic in both groups, Sensitivity to the studied Probiotic, Pregnant or lactating women, Chronic users of non-steroidal anti-inflammatory drugs.

Intervention groups

In the intervention group, probiotic capsules containing three strains of probiotic bacteria including Lactobacillus acidophilus, Bifidobacterium lactis and Bifidobacterium longum will be given to them and it is recommended to take one capsule daily in the first two weeks. In the control group, participants will receive capsules containing maltodextrin prepared in both color and shape of the product capsules.

Main outcome variables

VAS visual scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211226053534N1**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Elham Mokhtari Amirmajdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 316 5096

Email address

emokhtaria@mshdiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of probiotics on gastrointestinal symptoms in patients with gastric cancer

Public title
Evaluation the effect of probiotics on gastrointestinal symptoms in patients with gastric cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18 to 70 years Endoscopically confirmed gastric cancer and pathology that are in the recovery phase (their treatment is over) Refer to the gastroenterology clinic of Azad University of mashhad educational hospitals Informed consent to enter the study
Exclusion criteria:
 Obvious neurological disease Probiotic consumption in the past month Dissatisfaction with inclusion in the study Lack of patient cooperation Lack of proper use of the Probiotic in both groups Sensitivity to the studied Probiotic Pregnant or lactating women Chronic users of non-steroidal anti-inflammatory drugs

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this way, the allocation of samples to test or control groups will be done by random allocation (using blocking). The use of blocking will be done on different days due to the allocation of samples. In this method, the groups are first identified by giving the code to the groups that will be group A: intervention and B: control. 5 blocks of 6 are specified: 1- AABBAB, 2- BBAABA, 3- AABABB, 4-BABABA, 5-BBBAAA, 6- AAABBB. Finally, they are included in the study and placed in the intervention and control groups, respectively. After completing the first 5 blocks, the second block will be sampled.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will not be informed about which group they will be in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
 Islamic Azad University - Mashhad Branch (Research Ethics Committee)
Street address
 Islamic Azad University School of Medicine,Imam khomeini14 Aven, Mashhad
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9187147578
Approval date
 2021-06-23, 1400/04/02
Ethics committee reference number
 IR.IAU.MSHD.REC.1400.048

Health conditions studied
1
Description of health condition studied
 Gasteric cancer
ICD-10 code
 C16.9
ICD-10 code description
 Malignant neoplasm of stomach, unspecified

Primary outcomes
1
Description
 VAS visual scale for Gastrointestinal symptoms such as abdominal pain, diarrhea, constipation and bloating
Timepoint
 Before the intervention and at the end of the fourth and eighth weeks
Method of measurement
 VAS visual scale

2
Description
Timepoint
Method of measurement

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: Probiotic capsule containing three strains of probiotic bacteria including Lactobacillus acidophilus, Bifidobacterium lactis and Bifidobacterium longum and is one the products of Gostaresh Milad Pharmed Company will be provided to them and it is recommended that they take one capsule a day in the first two weeks.

Category

Treatment - Drugs

2

Description

Control group: participants will receive capsules containing maltodextrin prepared in both color and shape of the product capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Dr. Elham Mokhtari Amir Majdi

Street address

BaBa Nazr 39, Kuy-e-Tollab

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Province

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Phone

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Web page address

2

Recruitment center

Name of recruitment center

Aria Hospital

Full name of responsible person

Dr. Elham Mokhtari Amir Majdi

Street address

Golestan sharghi Ave, Chamran St

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.Toraj zandbaf

Street address

School of Medicine,Imam khomeini14 Aven, Mashhad

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Elham Mokhtari Amirmajdi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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