# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 complted 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**
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Iran (Islamic Republic of)
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**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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**2**

**Recruitment center**
**Name of recruitment center**
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## Sponsors / Funding sources

**1**

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Islamic Azad University
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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
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## Person responsible for updating data

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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