Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Study of the potential radioprotective effects of probiotic bacteria to mitigate gastrointestinal complications of colorectal cancer after conventional radiotherapy

Protocol summary

Study aim

Evaluation of the effect of probiotic bacteria on quality of life, blood factors and reduction of gastrointestinal complications after conventional radiotherapy procedures in patients with colorectal cancer

Design

This is a double-blind randomized clinical trial study. Randomization will be done by computer software. 60 patients with colorectal cancer will be selected in the study. Patients will be divided to receive probiotic supplements or placebo.

Settings and conduct

This clinical trial will be performed in the oncology radiotherapy unit of Namazi Hospital in Shiraz. Patients with colorectal cancer will be divided in one of the probiotic or placebo groups.

Participants/Inclusion and exclusion criteria

Admission criteria are adults who have colorectal cancer (colon and rectum) and will be treated with radiotherapy and their age is 18 to 90 years. Exclusion criteria include the use of narcotic analgesics, acute and chronic gastrointestinal complications before treatment, use of any antibiotics in a week before the start of radiotherapy unless prescribed by a doctor, dissatisfaction with continued treatment, non-adherence to the treatment regimen, Do not use any probiotic supplements, including probiotic yogurt for 15 days before starting treatment, do not use anti-diarrheal drugs (unless prescribed by a doctor) and do not receive radiation therapy in the abdomen and pelvis in previous years.

Intervention groups

Group 1: 2 probiotic capsules daily from one week before the start of treatment to ten days after the end of treatment Group 2: 2 probiotic capsules daily from one week after the start of treatment to ten days after the end of treatment Group 3: 2 probiotic placebo capsules daily

Main outcome variables

Quality of life, Gastrointestinal symptoms, Blood factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210704051788N1**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**
Update count: **0**

Registration date

2021-10-10, 1400/07/18

Registrant information

Name

Hamidreza Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 9332

Email address

jamalihamidreza91@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-12, 1400/07/20

Expected recruitment end date

2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the potential radioprotective effects of probiotic bacteria to mitigate gastrointestinal complications of colorectal cancer after conventional radiotherapy

Public title

Study of the potential radioprotective effects of probiotic bacteria to mitigate gastrointestinal complications after conventional radiotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults with colorectal cancer who are candidates for radiotherapy as part of their treatment

Exclusion criteria:

Consumption of narcotic painkillers Existence of acute and chronic gastrointestinal complications before starting treatment Take any antibiotics one week before the start to end of radiotherapy Received radiation therapy in the abdomen and pelvis in recent years Use probiotic supplements during the 15 days before the study and also take other probiotic forms including probiotic yogurt and other fermented foods

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly assigned to three groups to receive probiotics one week before the start of radiotherapy (n = 20), one week after the start of radiotherapy (n = 20) or placebo (n = 20).

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization will be hidden from researchers and participants until the statistical analysis is completed.Another person who has no role in this clinical trial and is not aware of random allocation gives the capsules to participants.

Placebo

Used

Assignment

Parallel

Other design features

Participants will take probiotics for up to ten days after completing radiotherapy

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences -Zand Blvd

City

Shiraz

Province

Fars

Postal code

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Approval date

2021-09-11, 1400/06/20

Ethics committee reference number

IR.SUMS.REC.1400.457

Health conditions studied

1

Description of health condition studied

Colorectal Cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

2

Description of health condition studied

Colorectal Cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

Quality of life

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Questionnaire

2

Description
Gastrointestinal disorders
Timepoint
At the beginning of the study and 6 months after the intervention
Method of measurement
Clinical examination by an oncologist

Secondary outcomes

1

Description
Thrombocytopenia-Leukopenia-Anemia
Timepoint
At the beginning of the study and 8 weeks after the intervention
Method of measurement
CBC Test(Complete blood count)

Intervention groups

1

Description
Intervention group: 1-Patients will take two capsules (daily) containing several probiotic strains from one week before the start of treatment until 10 days after the end of radiotherapy.
Category
Treatment - Drugs

2

Description
Intervention group: 2-Patients will take two capsules (daily) containing several probiotic strains from one week after the start of treatment to 10 days after the end of radiotherapy.
Category
Treatment - Drugs

3

Description
Control group: Two placebo capsules daily for ten days after the end of radiotherapy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Dr.Hamid Nasrollahi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Abbas Rezaeianzadeh
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7134814336
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vcrdep@sums.ac.ir
Web page address
Grant name
Grant code / Reference number
22054
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person

Hamidreza Jamali
Position
Master of Medical Physics
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Master
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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
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
Title and more details about the data/document
All data can be shared without personal information
When the data will become available and for how long
6 months after the publication of the results will be given access
To whom data/document is available
It will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
All requests will be reviewed by the person in charge of public responses
From where data/document is obtainable
All applicants should send their request to jamalihamidreza91@yahoo.com
What processes are involved for a request to access data/document
Requests will be processed within two weeks and the response will be emailed to the applicant.
Comments