Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of a Low-FODMAPs Diet (Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols) on Gastrointestinal Symptoms , Quality of Life and performance status in Cancer Patients Receiving Abdominal and pelvic Radiotherapy: An Interventional Study

Protocol summary

Study aim
This study aims to investigate the effect of a low-FODMAP diet on gastrointestinal symptoms and quality of life in cancer patients receiving radiotherapy to the abdominal and pelvic regions.

Design
Pragmatic, community based, parallel group, randomised controlled trial

Settings and conduct
Initially, a list of eligible patients will be obtained from the radiotherapy center, and a demographic information form will be completed for each patient. Then, the low-FODMAP diet will be explained to patients in the intervention group, and the relevant dietary instructions will be provided to them. Patients will be divided into two groups: an intervention group, which will receive the low-FODMAP diet from the start of radiotherapy for 5 weeks and up to 2 weeks after completion of treatment, and a control group, which will continue their usual diet. Quality of life will be assessed using the EORTC QLQ-C30 questionnaire, and patients' performance status will be evaluated at the beginning, during, and at the end of radiotherapy. Finally, quality of life, gastrointestinal symptoms, and performance status will be compared between patients adhering to the low-FODMAP diet and those following their usual diet.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Consent to participate and ability to complete study procedures Histopathologically confirmed cancer Candidate for radical or adjuvant radiotherapy Adequate renal, hepatic, and bone marrow function Exclusion Criteria Refusal to participate Prior radiotherapy Severe active disease, including IBS Distant metastatic cancer

Intervention groups
Low-FODMAPs Diet (Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols)

Main outcome variables
Assessment of gastrointestinal symptoms, quality of life, and performance status in cancer patients receiving radiotherapy to the abdominal and pelvic regions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260515069409N1**
Registration date: **2026-08-12, 1405/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-12, 1405/05/21**
Update count: **0**

Registration date
2026-08-12, 1405/05/21

Registrant information

Name
zeinab ghaeminejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-01, 1405/05/10

Expected recruitment end date
2026-11-21, 1405/08/30
Actual recruitment start date
2026-08-01, 1405/05/10
Actual recruitment end date
2026-11-21, 1405/08/30
Trial completion date
2026-12-21, 1405/09/30

Scientific title
Effect of a Low-FODMAPs Diet (Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols) on Gastrointestinal Symptoms , Quality of Life and performance status in Cancer Patients Receiving Abdominal and pelvic Radiotherapy: An Interventional Study

Public title
Investigating the effect of a Low-FODMAP diet in cancer patients undergoing radiotherapy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate and ability to complete the study procedures. Histopathologically confirmed diagnosis of cancer. Candidate for radical or adjuvant radiotherapy. Adequate renal, hepatic, and bone marrow function. Aged between 18 and 75 years.
Exclusion criteria:
Unwillingness to cooperate. History of prior radiotherapy. Presence of severe active disease, including IBS. Patients with distant metastatic cancer.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Procedure In this study, after assessing the eligibility criteria and obtaining written informed consent, participants will be randomly allocated into two groups: the intervention group (receiving the Low-FODMAP diet) and the control group (usual diet). 1. Type and method of randomization: This study will use simple randomization with a 1:1 allocation ratio. A random number table will be used to generate the random allocation sequence. 2. Unit of randomization: The unit of randomization is the individual participant (patient). Each eligible participant, after enrollment and assignment of an identification code, will be allocated to one of the two study groups. 3. Tool and method for generation of the random sequence: The random allocation sequence will be generated by a person who is not involved in participant recruitment or eligibility assessment, using a random number table. For each participant number, group assignment will be determined based on the selected random number (e.g., odd/even numbers corresponding to one of the two groups). The final randomization sequence will be prepared and documented before the start of the study. 4. Allocation concealment: To prevent selection bias, the random allocation sequence will be placed in sequentially numbered, opaque, sealed, and non-transparent envelopes. At the time of enrollment, the researcher will open only the next envelope in sequence, and the participant will be assigned to the corresponding group according to the card inside the envelope. Therefore, the researcher will remain unaware of the group assignment until the envelope is opened. 5. Stratified randomization: Stratified randomization will not be used in this study, and all participants will undergo simple randomization without stratification.
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
Research Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
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tehran
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Postal code
1981619573
Approval date
2025-12-16, 1404/09/25
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1404.041

Health conditions studied

1

Description of health condition studied
Abdominopelvic cancers, radiotherapy, and a low-FODMAP diet.
ICD-10 code

C64-C68

ICD-10 code description

Malignant neoplasms of urinary tract

Primary outcomes

1

Description

Quality of Life (QoL) score

Timepoint

Before the start of radiotherapy, one week after initiation, at the end of the third week, and at the end of the radiotherapy course (weeks 5–7).

Method of measurement

Quality of Life (QoL) score

2

Description

Gastrointestinal Symptoms

Timepoint

Before the start of radiotherapy, one week after initiation, at the end of the third week, and at the end of the radiotherapy course (weeks 5–7).

Method of measurement

Toxicity criteria of the Radiation Therapy Oncology Group (RTOG), PRSS score

3

Description

performance status

Timepoint

Before the start of radiotherapy, one week after initiation, at the end of the third week, and at the end of the radiotherapy course (weeks 5–7).

Method of measurement

Performance status assessment in cancer patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Low-FODMAPs Diet (Fermentable Oligosaccharides, Disaccharides, Monosaccharides, and Polyols)

Category

Treatment - Other

2

Description

Control group: Control group: a regular diet for weight maintenance.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital, Tehran

Full name of responsible person

Zeinab Ghaeminejad

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Darbands Street, Ghods Square, Tajrish, Tehran

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2

Recruitment center

Name of recruitment center

Salamat Farda Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ehsan Hejazi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Ehsan Hejazi

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)

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