

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of nutritional consultation on gastrointestinal complications in patients undergoing radiotherapy of abdominal and pelvic cavity cancer

Protocol summary

Study aim

The effect of nutritional consultant on reduce the gastrointestinal complications

Design

After confirming the inclusion criteria and obtain written inform consent, patients were randomly allocating into two groups (using table of random numbers and sealed envelopes used to hide). In the first or intervention group educational program will be given to the patient by the researcher during 3 sessions of an hour in three times a week (during two weeks) and second or non-intervention group, intervention not given. Sample size in study is 80.

Settings and conduct

Patients that referred to Towhid Hospital in Sanandaj city will included in study. After confirming the inclusion criteria and obtain written inform consent, patients were randomly allocating into two groups (using table of random numbers and sealed envelopes used to hide). This trial is double blind.

Participants/Inclusion and exclusion criteria

The inclusion criteria is following: Mean age 44-84 years, Diagnostic abdominal and pelvic cavity cancer pathology. Receive abdominal and pelvic cavity radiotherapy. Patients should be at least one-week radiotherapy. Exclusion criteria is following: Patients with colon cancer Chronic digestive disorders The history of Gluten and Celiac intolerance

Intervention groups

Intervention group: will be given nutritional consultant to the patient by the researcher during 3 sessions of an hour in three times a week (during two weeks), individually and face-to-face at the Radiotherapy Hospital of Tohid Hospital. Control group: In this group intervention will not done.

Main outcome variables

Nausea, Vomiting, Abdominal bloating, Diarrhea and Constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040031N1**

Registration date: **2019-04-12, 1398/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-12, 1398/01/23**

Update count: **0**

Registration date

2019-04-12, 1398/01/23

Registrant information

Name

rozhin khateri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3557 2282

Email address

khateri.r@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nutritional consultation on gastrointestinal complications in patients undergoing radiotherapy of abdominal and pelvic cavity cancer

Public title

The effect of nutritional consultation on gastrointestinal complications

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 84 -18 years Diagnostic abdominal and pelvic cavity cancer pathology Receive abdominal and pelvic cavity radiotherapy Patients should be at least one-week radiotherapy

Exclusion criteria:

Patients with colon cancer Chronic digestive disorders The history of Gluten and Celiac intolerance

Age

From **18 years** old to **84 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After confirming the inclusion criteria and obtain written inform consent, patients were randomly allocate into two groups (using table of random numbers).

Blinding (investigator's opinion)

Double blinded

Blinding description

Opaque sealed envelopes numbered sequentially with the group type written in them will used for allocation concealment. The envelopes will prepared by a researcher not involved in data collection. The envelopes will opened after completing the pre-intervention questionnaires. Therefore, before random assignment of participants, outcome assessor and participants will unaware of what participants were assigned to each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences, Kurdistan ,Iran

Street address

Head on Hotel Shadi, Pasdaran Street, Kurdistan

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.MUK.REC.1397.286

Health conditions studied

1

Description of health condition studied

Abdominal cancer

ICD-10 code

C76.2

ICD-10 code description

Malignant neoplasm of other and ill-defined sites (Abdomen)

2

Description of health condition studied

Pelvic cancer

ICD-10 code

C76.3

ICD-10 code description

Malignant neoplasm of other and ill-defined sites (Pelvis)

Primary outcomes

1

Description

Nausea

Timepoint

After intervention

Method of measurement

Gastrointestinal Symptom Rating Scale

2

Description

Vomiting

Timepoint

After intervention

Method of measurement

Gastrointestinal Symptom Rating Scale

3

Description

Abdominal bloating
Timepoint
After intervention
Method of measurement
Gastrointestinal Symptom Rating Scale

4

Description
Diarrhea
Timepoint
After intervention
Method of measurement
Gastrointestinal Symptom Rating Scale

5

Description
Constipation
Timepoint
After intervention
Method of measurement
Gastrointestinal Symptom Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: educational consultation will be given to the patient by the researcher during 3 sessions of an hour a week (during two weeks).
Category
Prevention

2

Description
Control group: intervention not given.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Towhid hospital
Full name of responsible person
Rozhin Khateri
Street address
Towhid hospital, Graishian St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Ebrahim Ghaderi
Street address
Head on Hotel Shadi, Pasdaran Street, Kurdistan
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6617713446
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Email
ghaderie@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
rozhin khateri
Position
Student Master of Medical Surgical Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Full name of responsible person

Mokhtar Yaghobi

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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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