Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of the Mediterranean diet on nutritional status, muscle mass and strength, and inflammatory factors in patients with colorectal cancer cachexia: A randomized controlled clinical trial

Protocol summary

Study aim

This clinical trial study aims to evaluate the effect of the Mediterranean diet on nutritional status, muscle mass and strength, and inflammatory markers in patients with colorectal cancer cachexia.

Design

Clinical trial with control group and parallel design, randomized on over 40 patients with colorectal cancer cachexia

Settings and conduct

This study is a randomized controlled clinical trial on 40 patients with colorectal cancer cachexia. Stratified block randomization will be performed based on the type of cancer (colon or rectum). Participants in the intervention group receive a Mediterranean diet menu, but participants in the control group receive nutritional advice for cancer patients and dietary recommendations for weight gain. The duration of the study for both intervention and control groups is 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Colorectal cancer in clinical stage III-IV 2. Patients with cachexia according to the Global Leadership Initiative on Malnutrition (GLIM) criteria. 3. The functional status of patients according to the Karnofsky scale is at least ≥ 70%. 4. Patients who are not on enteral or parenteral nutrition. 5. Patients without acute uncontrolled underlying diseases such as renal failure and liver failure. Exclusion criteria: 1. Patients are on enteral or parenteral nutrition. 2. Patients with a history of food allergies to the components of the Mediterranean diet.

Intervention groups

The main intervention in this study is the administration of a Mediterranean diet. Based on the recommended food groups in the Mediterranean diet, a weekly menu will be set up for patients. For the control group, routine nutritional recommendations related to cancer patients as well as nutritional education necessary for weight gain will be given.

Main outcome variables

Nutritional status, muscle mass and strength, and inflammatory markers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211027052884N1**
Registration date: **2021-11-09, 1400/08/18**
Registration timing: **prospective**

Last update: **2021-11-09, 1400/08/18**
Update count: **0**

Registration date

2021-11-09, 1400/08/18

Registrant information

Name

Amir Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5742

Email address

abaqeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the Mediterranean diet on nutritional status, muscle mass and strength, and inflammatory factors in patients with colorectal cancer cachexia: A randomized controlled clinical trial

Public title
The effect of the Mediterranean diet on nutritional status, muscle mass and strength, and inflammatory factors in patients with colorectal cancer cachexia: A randomized controlled clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with colorectal cancers in stages III-IV according to TNM UICC 2010 method (based on the oncologist diagnosis). The patient has cachexia, which is defined according to the Global Leadership Initiative on Malnutrition (GLIM). Patients' functional status is at least ≥ 70% according to Karnofsky scale. Individuals who have no contraindications for oral feeding and be able to be fed orally. Patients without acute uncontrolled underlying diseases such as kidney and/or liver failure.
Exclusion criteria:
Patients who need supportive nutrition such as enteral or parenteral feeding. Patients with a history of allergy to any components of the Mediterranean diet, such as olive oil or nuts.
Age
From **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified block randomization will be performed based on the type of cancer (colon or rectum) using the site www.randomization.com. In this method, each group will be assigned one of the letters A and B, and randomization will be done in 4 blocks. This will be done for each type of cancer (colon or rectum) and two lists will be prepared for them. Within each class, patients will be randomly assigned to one of the two study groups in a 1: 1 ratio. The randomization process will be performed by someone outside the research team.
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
Ethics committee of Tehran University of Medical Sciences
Street address
Faculty of Nutrition and Dietetics, University of Medical Sciences and Health Services, Tehran, Keshavarz Blvd., Naderi St., Hojjatdoost Alley, No. 44
City
Tehran
Province
Tehran
Postal code
1416643931
Approval date
2021-09-01, 1400/06/10
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.601

Health conditions studied

1

Description of health condition studied
Colorectal cancer cachexia
ICD-10 code
R64
ICD-10 code description
Cachexia

Primary outcomes

1

Description
Nutritional status score
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
PG-SGA (Patient Generated-Subjective Global Assessment) questionnaire

2

Description
Muscle strength
Timepoint
Before the intervention - 8 weeks after the intervention

Method of measurement
Handgrip strength dynamometer

3

Description
Muscle mass
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
Bio-Electrical Impedance Analysis (BIA)

4

Description
Inflammatory markers (hs-CRP, IL-6, TNF-α)
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

1

Description
Body weight
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
Bio-Electrical Impedance Analysis (BIA)

2

Description
Fat mass
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
Bio-Electrical Impedance Analysis (BIA)

3

Description
Quality of life and treatment complications (diarrhea, nausea, constipation, vomiting and appetite)
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
EORTC QLQ-C30 (The European Organization for Research and Treatment of Cancer quality of life questionnaire)

4

Description
Albumin and Total Protein
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
Autoanalyzer (spectrophotometric method)

5

Description
Complete Blood Count (CBC)
Timepoint
Before the intervention - 8 weeks after the intervention
Method of measurement
cell counter

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive a Mediterranean diet menu. For this purpose, the energy required by the patients in the intervention group, according to the recommendations of the ASPEN guideline, is first considered 25 kcal per kg of body weight (current weight of patients), and then gradually over two weeks, this amount will be considered up to 35 kcal per kg of body weight. This calorie will be divided as follows: 35% of calories from fat, 45% of calories from carbohydrates, and 20% of calories from protein. Then, the sources of these macronutrients from different food groups will be considered based on the Mediterranean diet pyramid. Moreover, based on these food groups, a weekly menu will be set up for patients. To follow this diet, extra virgin olive oil will be given to patients.
Category
Lifestyle

2

Description
Control group: Participants in the control group will receive nutritional advice for cancer patients and dietary recommendations for weight gain
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Amir Bagheri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tehran 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
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Amir Bagheri
Position
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol will be written and published in the form of an article. The clinical results of the study will be published in the form of an article.
When the data will become available and for how long
9 months after the end of the study
To whom data/document is available
The information will be made available to the public.
Under which criteria data/document could be used
To use the findings in the clinic or to write other articles, including review articles. In the case of original articles, researchers will be allowed to do so.
From where data/document is obtainable
Update information via email to the person in charge
What processes are involved for a request to access data/document
After receiving the request from the person in charge of updating, the study will be provided to the researcher in consultation with the scientific officer.
Comments