

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 $\geq 70\%$. 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 $\geq 70\%$ 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammadjavad Hosseinzadeh

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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**

Tehran University of Medical Sciences

Full name of responsible person

Amir Bagheri

Position

Ph.D Student

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Professor of nutrition

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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