

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effects of vitamin D and omega-3 fatty acids co-supplementation on inflammatory biomarkers, tumor marker CEA, and nutritional status in patients with colorectal cancer

Protocol summary

Study aim

Evaluation of the effect of vitamin D and omega-3 fatty acids co-supplementation on inflammatory biomarkers, tumor marker CEA, and nutritional status in patients with colorectal cancer

Design

An 8 weeks' double blind randomized controlled trial to determine the effects of vitamin D and omega-3 fatty acids co-supplementation on inflammatory biomarkers, tumor marker CEA, and nutritional status in patients with colorectal cancer.

Settings and conduct

The participants, who meet the criteria, will be randomly allocated into 4 groups. Blood samples were taken to quantify serum level of 25(OH)D, TNF- α , IL-8, NF-kB, CRP, and tumor marker CEA at study baseline and after 8 weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with stage II or III colorectal cancer if they have to begin chemotherapy; aged 18 years or more; BMI range of 18.5-30 kg/m²; not having any chronic disease; no taking vitamin - mineral supplements or parenteral nutrition; not taking laxative, anti-inflammatory and blood thinner medications; absence of allergic to fish and fish products, and history of having other cancers. Exclusion criteria: Affecting by any acute disease during the study; changing the drug regimen; refusing to continue the chemotherapy; unwilling to continue the study; patients who had less than 90% compliance with treatment.

Intervention groups

The intervention groups will be randomly allocated into 3 groups: 1) a 50000 IU vitamin D per l, weekly+ 2 omega-3 fatty acid capsules, daily, each capsule containing 330 mg omega-3 fatty acid; 2) a 50000 IU vitamin D per l, weekly+ 2 omega-3 fatty acid placebo, daily; 3) a vitamin D placebo, weekly+ 2 omega-3 fatty

acid capsules.

Main outcome variables

Serum level of TNF- α ; tumor marker CEA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180306038979N1**

Registration date: **2018-03-16, 1396/12/25**

Registration timing: **prospective**

Last update: **2018-03-16, 1396/12/25**

Update count: **0**

Registration date

2018-03-16, 1396/12/25

Registrant information

Name

Behnaz Abiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8253

Email address

abiri.b@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

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

Effects of vitamin D and omega-3 fatty acids co-supplementation on inflammatory biomarkers, tumor marker CEA, and nutritional status in patients with colorectal cancer

Public title

Effects of vitamin D and omega-3 fatty acids co-supplementation on inflammatory biomarkers, tumor marker CEA, and nutritional status in patients with colorectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with stage II or III colorectal cancer if they have to begin chemotherapy; Aged 18 years or more; BMI range of 18.5-30 kg/m²; Serum 25(OH)D < 30 ng/ml; Not having autoimmune disease, diabetes, hypertension, renal, hepatic, parathyroid, and gastrointestinal disorders; No taking vitamin D and/or omega-3 supplements and other vitamin- mineral supplements or parenteral nutrition; Not taking laxative, anti-inflammatory and blood thinner medications; Absence of allergic to fish and fish products, and history of having other cancers.

Exclusion criteria:

Affecting by any acute disease during the study; Changing the drug regimen; refusing to continue the chemotherapy; Unwilling to continue the study; Patients who had less than 90% compliance with treatment.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were allocated randomly and by using a random number table, into one of four groups. Vitamin D, omega-3, and placebo tablets were placed into identical containers, and a person who is not involved in study protocol created the randomization list. All investigators, and participants were blinded to the random assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, study leader who is not involved in study protocol created the randomization list assigning participants to the vitamin D, omega-3, or the placebo group. Vitamin D, omega-3, and placebo tablets are placed into unlabeled identical containers. The study leader will label these containers with participant numbers using the randomization list. All investigators, and participants were blinded to the random assignments.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences,

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Highway, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.AJUMS.REC.1396.1077

Health conditions studied**1****Description of health condition studied**

Colorectal cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes**1****Description**

Serum level of TNF- α .

Timepoint

Before and 8 weeks after intervention.

Method of measurement

Serum TNF- α levels will be assessed by ELISA and Bender Med kit (Bender Med, Germany).

Secondary outcomes

1

Description

Tumor marker CEA.

Timepoint

Before and 8 weeks after intervention.

Method of measurement

Tumor marker CEA will be assessed by ELISA and CanAg kit (CanAg, Italy).

Intervention groups

1

Description

Intervention 1: a 50000 IU vitamin D per l, weekly+ 2 omega-3 fatty acid capsules, daily

Category

Treatment - Drugs

2

Description

Intervention group 2: a 50000 IU vitamin D per l, weekly+ 2 omega-3 fatty acid placebo, daily

Category

Treatment - Drugs

3

Description

Intervention group 3: two omega-3 fatty acid capsules+ a vitamin D placebo, weekly

Category

Treatment - Drugs

4

Description

Control group: a vitamin D placebo, weekly+ 2 omega-3 fatty acid placebo, daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology clinic of Tehran Gastroenterology & Hepatology Center (TGHC)

Full name of responsible person

Dr. Masood Iravani

Street address

Amir Abad, 19th St, No. 144

City

Tehran

Province

Tehran

Postal code

1439963553

Phone

+98 21 8801 6980

Email

behnaz.abiri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

Street address

Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3336 2414

Email

behnaz.abiri@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Haidari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Golestan Highway

City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8253
Email
haidari_f@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Vafa
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hemat Express way
City
Tehran
Province
Tehran
Postal code
61357-15794
Phone
+98 21 8670 4734
Email
vafa.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Behnaz Abiri
Position
Ph.D. Student
Latest degree
Master
Other areas of specialty/work
Nutrition

Street address
Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8253
Email
behnaz.abiri@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Primary and secondary outcome measures of the participants.

When the data will become available and for how long

Starting 1 year after publication.

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Using the data in literature review

From where data/document is obtainable

Email addresses

What processes are involved for a request to access data/document

Request the data sending email.

Comments