Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of vitamin D, omega 3 fatty acids supplementation and co-supplementation of them on liver, inflammatory biomarkers, and oxidative stress in patients with colorectal cancer

Protocol summary

Study aim

Evaluation of the effect of vitamin D, omega 3 fatty acids supplementation and co-supplementation of them on liver, inflammatory biomarkers, and oxidative stress in patients with colorectal cancer

Design

The study is done in Phase 3 clinical trials with a control group, in a factorial design, double-blind and randomized allocation. 80 eligible colorectal cancer patients were randomly allocated into 4 groups (vitamin D, omega-3, co-supplementation, placebo). For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks.

Settings and conduct

The participants, in Oncology clinic of Tehran Gastroenterology & Hepatology Center, who meet the criteria, will be randomly allocated into 4 groups. Blood samples were taken to quantify serum levels of 25(OH)D, and liver enzymes at baseline and after 8 weeks of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with stage II or III colorectal cancer and were candidate to receive chemotherapy; Aged 18 years or more; BMI range of 18.5-30 kg/m2; Serum 25(OH)D < 30 ng/ml; Not having autoimmune or chronic diseases; No taking vitamin D and/or omeaga-3 supplements and other vitamin- mineral supplements; Not taking laxative and anti-inflammatory medications; Not allergic to fish and fish products.

Intervention groups

The intervention groups, for an 8-week period, will be randomly allocated into 4 groups: 1) a 50000 IU vitamin D tablet (Zahravi, Iran), weekly+ 2 omega-3 fatty acid capsules (each capsule containing 330 mg omeg-3 fatty acid), daily (Minami Nutrition, Belgium); 2) a 50000 IU vitamin D tablet, weekly+ 2 omega-3 fatty acid placebo (Zahravi, Iran), daily; 3) a vitamin D placebo (Zahravi, Iran), weekly+ 2 omega-3 fatty acid capsules; 4) a vitamin D placebo, weekly+ 2 omega-3 fatty acid placebo, daily.

Main outcome variables

Serum level of TNF-α

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N22**
Registration date: **2018-12-30, 1397/10/09**
Registration timing: **prospective**

Last update: **2018-12-30, 1397/10/09**
Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D, omega 3 fatty acids supplementation and co-supplementation of them on liver, inflammatory biomarkers, and oxidative stress in patients with colorectal cancer

Public title

Effect of vitamin D and omega 3 fatty acids co-supplementation on colorectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with stage II or III colorectal cancer and were candidate to receive chemotherapy; aged 18 years or more; body mass index range of 18.5-30 kg/m2; serum 25(OH)D < 30 ng/ml; not having autoimmune or chronic diseases; not taking vitamin D and/or omeaga-3 supplements and other vitamin- mineral supplements or parenteral nutrition; not taking laxative and anti-inflammatory medications; not allergic to fish and fish products;

Exclusion criteria:

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

For randomized allocation performing, permuted block randomization will be used by quadrilateral blocks. According to the sample size of 80 subjects, 20 blocks will be generated using the online site (www.sealedenvelope.com). In order to allocation concealment in the randomized process, unique codes will be used on the drug boxes that is generated by the software. Participants will enter based on the sequence produced into study and the drug packets with code registered will allocate to the individual. Therefore, before participants selection, they will be unaware of the type of intervention that will receive, as well as a random sequence produced during the study will be immune from prediction.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, a person who is not involved in study protocol created the randomization list assigning participants to the vitamin D, omega-3, co-supplementation 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

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical of Sciences

Street address

Iran University of Medical Science, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-12-13, 1397/09/22

Ethics committee reference number

IR.IUMS.REC.1397.572

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
Serum levels of Matrix Metalloproteinase-2 (MMP-2)
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum levels of MMP-2 will be assessed by ELISA and Zellbio kit (Zellbio, Germany).

2

Description
Serum levels of Matrix Metalloproteinase-9 (MMP-9)
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum levels of MMP-9 will be assessed by ELISA and Zellbio kit (Zellbio, Germany).

3

Description
Serum levels of Alkaline phosphatase (ALP)
Timepoint
Before and 8 weeks after intervention.
Method of measurement
Serum levels of ALP will be assessed by ELISA and Zellbio kit (Zellbio, Germany).

Intervention groups

1

Description
Intervention 1: a 50000 IU vitamin D tablet (Zahravi, Iran), weekly+ 2 omega-3 fatty acid capsules (each capsule containing 330 mg omega-3 fatty acid) (Minami Nutrition, Belgium), daily, for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: a 50000 IU vitamin D tablet (Zahravi, Iran), weekly+ 2 omega-3 fatty acid placebo (Zahravi, Iran), daily, for 8 weeks.
Category
Treatment - Drugs

3

Description
Intervention group 3: two omega-3 fatty acid capsules (each capsule containing 330 mg omega-3 fatty acid) (Minami Nutrition, Belgium), daily+ a vitamin D placebo (Zahravi, Iran), weekly, for 8 weeks.
Category
Treatment - Drugs

4

Description
Control group: a vitamin D placebo (Zahravi, Iran), weekly+ 2 omega-3 fatty acid placebo (Zahravi, Iran), daily, for 8 weeks.
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Province
Tehran
Postal code
1449614535
Phone
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Email
malakoutik@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Iran 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
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
A part of the data will be shared, such as primary outcomes.

When the data will become available and for how long
4 months after the publication of the results.

To whom data/document is available
researchers and students of university.

Under which criteria data/document could be used

Four months after the publication of this study papers, the obtained data will be available to the applicant researchers and students for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

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

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

Comments