

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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/m<sup>2</sup>; Serum 25(OH)D < 30 ng/ml; Not having autoimmune or chronic diseases; No taking vitamin D and/or omega-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 omega-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- $\alpha$

#### 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)

##### Phone

+98 21 8670 4734

##### Email address

vafa.m@iums.ac.ir

##### 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/m<sup>2</sup>; serum 25(OH)D < 30 ng/ml; not having autoimmune or chronic diseases; not taking vitamin D and/or omega-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- $\alpha$ .

**Timepoint**

Before and 8 weeks after intervention

**Method of measurement**

Serum TNF- $\alpha$  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

No. 144, 19th St, Amir Abad.

##### City

Tehran

##### Province

Tehran

##### Postal code

1439963553

##### Phone

+98 21 8801 6980

##### Email

iravani\_m@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Kazem Malakouti

##### Street address

Iran University of Medical Sciences, Hemat Express way

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86701

##### 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  
**Street address**  
Nutrition Department, School of Public Health, Iran  
University of Medical Sciences, Hemat Express way,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۹۶۱۴۵۳۵  
**Phone**  
+98 21 8670 4734  
**Email**  
rezavafa@yahoo.com

## 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**  
Nutrition Department, School of Public Health, Iran  
University of Medical Sciences, Hemat Express way,  
Tehran  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۹۶۱۴۵۳۵  
**Phone**  
+98 21 8670 4743  
**Email**  
rezavafa@yahoo.com

## Person responsible for updating data

**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**  
Nutrition Department, School of Public Health, Iran  
University of Medical Sciences, Hemat Express way,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۴۹۶۱۴۵۳۵  
**Phone**  
+98 21 8670 4743  
**Email**  
rezavafa@yahoo.com

## 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**