Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 perl, weekly+ 2 omega-3 fatty acid capsules, daily, each capsule containing 330 mg omeg-3 fatty acid; 2) a 50000 IU vitamin D perl, 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)

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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 omeaga-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 perl, weekly+ 2 omega-3 fatty acid capsules, daily
Category
Treatment - Drugs

2

Description
Intervention group 2: a 50000 IU vitamin D perl, 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
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Amir Abad, 19th St, No. 144
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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