Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of conjugated linoleic acid supplementation on nutritional status,serum conjugated linoleic acid levels, matrix metalloproteinases enzymes , inflammatory and oxidative factors in colorectal cancer patients undergoing chemoradiotherapy

Protocol summary

Summary

The aim of this study is to determine the effects of CLA supplementation on nutritional status, matrix metalloproteinases enzymes , inflammatory and oxidative factors in colorectal cancer patients undergoing chemo radiotherapy. Thirty colorectal cancer patients who refer for preoperative radiotherapy combined with chemotherapy comprising Fluorouracil regimen administrated concurrently with the first and the last 5 days of radiotherapy will be recruited. Patients will be assign into CLA and placebo groups and consume four 1000 mg capsules daily (providing 3 gr CLA) for 6 weeks or placebo. The supplementation begins 1 week before starting radiotherapy. At the onset and the end of study body weight, nutritional status, symptoms of eating problems and dietary intake of patients will be assessed. Blood samples for biochemical parameters are collected after an overnight fast (12 h) in to tubes before radiotherapy and at the end of intervention.The serum conjugated linoleic acid ,MDA,TAS,IL 1,IL6,TNF-α,hsCRP,Albumin, matrix metalloproteinases enzymes -2,9,liver enzymes and tumor marker (CEA) are determined before and after intervention.

General information

Acronym

ma

IRCT registration information

IRCT registration number: **IRCT201012041197N9**
Registration date: **2011-07-31, 1390/05/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-31, 1390/05/09

Registrant information

Name
Reza Mahdavi
Name of organization / entity
Faculty of Health & Nutrition, Tabriz UniV. of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7584
Email address
mahdavir@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutritional Reserch Center, Tabriz University of Medical Sciences

Expected recruitment start date

2011-07-31, 1390/05/09

Expected recruitment end date

2013-05-01, 1392/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of conjugated linoleic acid supplementation on nutritional status,serum conjugated linoleic acid levels, matrix metalloproteinases enzymes , inflammatory and oxidative factors in colorectal cancer patients undergoing chemoradiotherapy

Public title
Effects of conjugated linoleic acid supplemntation on nutritional status, matrix metalloproteinases enzymes , inflammatory and oxidative factors in colorectal cancer patients undergoing chemoradiotherapy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients with colorectal cancer in stage II and III undergoing preoperative radiotherapy combined with chemotherapy Exclusion criteria: renal and liver disease; diabetes mellitus; thyroid disorders; consumption of vitamin or mineral supplements; under weight(BMI<18.5); previous radiotherapy; history of other cancers and patients with clinical evidence of metastatic disease.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Daneshgah street,Tabriz university of Medical sciences
City
Tabriz
Postal code
Approval date
2011-07-25, 1390/05/03
Ethics committee reference number
9021

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C19
ICD-10 code description
Neoplasms,Digestive organs

Primary outcomes

1

Description
Serum conjugated linoleic acid
Timepoint
Before radiotherpay and at the end of intervention(6 weeks)
Method of measurement
Gas Chromatography

2

Description
Inflammatory factors(TNF-a, IL-1, IL-6, hs-CRP)
Timepoint
Before radiotherpay and at the end of intervention(6 weeks)
Method of measurement
Elisa kit, hs-CRP: kit immunoturbidimetry

Secondary outcomes

1

Description
Weight,
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
Weight:Scale

2

Description
Eating problem symptoms
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
Eating problem symptoms questionnaire

3

Description
Dietary inake of patients
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)

Method of measurement
24 hour food recall questionnaire

4

Description
TAS, MDA, Albumin
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
TAS, Albumin kit, MDA fluorimetry

5

Description
MMP-2, 9
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
MMP-2,9:kit

6

Description
Liver enzymes ,Tumor marker (CEA)
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
Liver enzymes ,Tumor marker(CEA):kit

7

Description
Nutritional status
Timepoint
Before radiotherapy and at the end of intervention
Method of measurement
PG-SGA questionnaire

Intervention groups

1

Description
In supplemented group,patients will consume four 1000 mg capsules daily (providing 3 gr CLA) for 6 weeks .Patients are instructed to take once at each of 3 mealtimes and once before bedtime. The supplementation begins 1 week before starting radiotherapy.
Category
Prevention

2

Description
In placebo group,patients will consume four placebo capsules daily for 6 weeks . Patients are instructed to take once at each of 3 mealtimes and once before bedtime. The intervention begins 1 week before starting radiotherapy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy Department of Emam Hospital
Full name of responsible person
Dr. Mohammad Mohammadzadeh
Street address
Radiotherapy Department , Emam Hospital,Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutritional Research Center,Tabriz University of Medical Sciences
Full name of responsible person
Dr. AliReza Ostad Rahimi
Street address
Facualty of Health and Nutrition,Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Research Center,Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Facualty of Health and Nutrition
Full name of responsible person
Dr. Reza Mahdavi
Position
Ph.D in Nutrition
Other areas of specialty/work

Street address
Facualty of Health and Nutrition,Tabriz University of Medical Sciences,Tabriz
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
Mahdavir@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Facualty of Health and Nutrition ,Tabriz
Full name of responsible person
Elnaz Faramarzi
Position
Ph.D candidate
Other areas of specialty/work
Street address
Facualty of Health and Nutrition ,Tabriz
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
elnazfaramarzi849@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Facualty of Health and Nutrition
Full name of responsible person
Elnaz Faramarzi
Position
Ph.D candidate
Other areas of specialty/work
Street address
City
Tabriz
Postal code
Phone
Fax
Email
elnazfaramarzie849@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty