

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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- $\alpha$ ,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

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##### 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 supplementation 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 radiotherapy 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 radiotherapy 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 intake 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**

Faculty 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**

Faculty of Health and Nutrition

**Full name of responsible person**

Dr. Reza Mahdavi

**Position**

Ph.D in Nutrition

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**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*