

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Fisetin supplementation on nutritional status, inflammatory and oxidative factors and matrix metalloproteinase enzymes in colorectal cancer patients receiving adjuvant chemotherapy in association with TYMS and MTHFR genes polymorphism

#### Protocol summary

##### Summary

The aim of the current study is to determine the effects of Fisetin supplementation on nutritional status, inflammatory and oxidative factors, matrix metalloproteinase enzymes and tumor markers including CA19-9, CEA and thymidine kinase1 in colorectal cancer patients receiving adjuvant chemotherapy in association with TYMS and MTHFR genes polymorphism. Forty two post-surgical colorectal cancer patients receiving chemotherapy regimens will be randomized into following two groups: Fisetin (A) and placebo(B). Group A and B will receive 100 mg Fisetin or placebo capsules every day for consecutive seven weeks, respectively. The intervention will be started seven days before the chemotherapy. Before the intervention, demographic characteristics of the participants will be collected. Further, 24h-food recall, PG-SGA, quality of life ( EORTC QLQ-CR29) and BMI of the subjects will be assessed using conventional methods. Furthermore, 10cc blood samples will be obtained after an overnight fasting at the end of intervention for subsequent determination of serum MDA,TAC,IL8, matrix metalloproteinases enzymes -7,9 and tumor markers of CA19-9, CEA and thymidine kinase. Finally, DNA will be extracted from the blood samples and polymorphism status of TYMS and MTHFR will be determined using PCR-RFLP.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015110511288N9**

Registration date: **2015-12-24, 1394/10/03**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-24, 1394/10/03

##### Registrant information

###### Name

Mohammad Alizadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1335 7313

###### Email address

mdalizadeh@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Nutrition Research Center, Tabriz University of Medical Science

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Fisetin supplementation on nutritional status, inflammatory and oxidative factors and matrix metalloproteinase enzymes in colorectal cancer patients receiving adjuvant chemotherapy in association with

TYMS and MTHFR genes polymorphism

## Public title

Effects of Fisetin supplementation on nutritional and inflammatory status of colorectal cancer patients receiving adjuvant chemotherapy in association with TYMS and MTHFR genes polymorphism

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: patients with colorectal cancer in stage II and III; Life expectancy of more than 3 month; Ability to walk and perform personal tasks; menopause(women)  
Exclusion criteria: history of chemotherapy in recent 4 weeks; clinical evidence of other metastatic disease, renal and liver disease; diabetes mellitus; thyroid disorders; consumption of vitamin or mineral supplements; under weight(BMI<18.5)

## Age

From **18 years** old to **64 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **42**

## 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 Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2015-11-23, 1394/09/02

#### Ethics committee reference number

TBZMED.REC.1394.750

## 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 levels of Matrix Metalloproteinase-7 , 9 (MMP-7,9)

#### Timepoint

Before and after the intervention (7 weeks)

#### Method of measurement

EIISA

## Secondary outcomes

### 1

#### Description

BMI

#### Timepoint

Before and after intervention (7 weeks)

#### Method of measurement

scale with stadiometer

### 2

#### Description

Interleukin 8

#### Timepoint

Before and after intervention (7 weeks)

#### Method of measurement

ELISA

### 3

#### Description

Chemotherapy related Eating issues

#### Timepoint

Before and after intervention (7 weeks)

#### Method of measurement

questionnaire

### 4

#### Description

Dietary intake of patients

#### Timepoint

Before and after intervention (7 weeks)

#### Method of measurement

24-h food Recall

## 5

### **Description**

MDA and Total antioxidant capacity(TAC)

### **Timepoint**

Before and after intervention (7 weeks)

### **Method of measurement**

Elisa kit - fluorimetry

## 6

### **Description**

CEA, CA19-9 and thymidine kinase 1

### **Timepoint**

Before and after intervention (7 weeks)

### **Method of measurement**

Elisa kit

## 7

### **Description**

Quality of life

### **Timepoint**

Before and after intervention (7 weeks)

### **Method of measurement**

Quality of life questionnaire (EORTC QLQ-CR29)

## 8

### **Description**

nutritional status

### **Timepoint**

Before and after intervention (7 weeks)

### **Method of measurement**

PG-SGA questionnaire

## 9

### **Description**

TYMS , MTHFR genotype

### **Timepoint**

Before intervention

### **Method of measurement**

PCR-RFLP

## **Intervention groups**

### 1

#### **Description**

Daily supplementation of one 100 mg capsule with food (starting from a week before chemotherapy until the end of second chemotherapy cycle ( a total of 7 weeks)

#### **Category**

Other

### 2

#### **Description**

Daily supplementation of one placebo capsule with food (starting form a week before chemotherapy until the end of second chemotherapy cycle ( a total of 7 weeks)

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Gastrointestinal clinic of Sina Hospital

##### **Full name of responsible person**

Dr. Kamal Boustani

##### **Street address**

##### **City**

Tabriz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Nutrition Research Center,Tabriz University of Medical

##### **Full name of responsible person**

Dr. AliReza Ostad Rahimi

##### **Street address**

Faculty of 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**

Nutrition Research Center,Tabriz University of Medical

#### **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**

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Faculty of Nutrition,Tabriz University of Medical Sciences,Tabriz

##### **Full name of responsible person**

Dr. Mohammad Alizadeh

##### **Position**

Ph.D. in Nutrition

**Other areas of specialty/work**

**Street address**

Daneshgah street, Tabriz university of Medical sciences Tabriz

**City**

Tabriz

**Postal code**

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**Fax**

**Email**

mdalizadeh@tbzmed.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**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*