

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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
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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