Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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
ElISA

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 و 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

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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