Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of synbiotic supplementation on dietary intake, nutritional status, quality of life, serum matrix metalloproteinase, serum inflammatory factors(TNFα,IL-6) and side effect of treatments in rectal patients undergoing neoadjuvant chemoradiotherapy

Protocol summary

Summary

Objectives: effects of synbiotic supplementation on dietary intake،nutritional status, quality of life, serum Matrix Metalloproteinase enzymes,serum inflammatory markers levels(TNFα,IL-6) and side effects of treatment in rectal cancer patients undergoing neoadjuvant chemoradiotherapy. Design: Double blind randomized clinical trial. Setting and conduct: forty-six rectal 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 randomly divided into two groups intervention (synbiotic) and control (placebo). Participants including major eligibility criteria: volunteer rectal cancer patients in stage 2 and 3. Intervention: Intervention group: consume 2 capsules daily for 6 weeks (1 week before starting radiotherapy to the end of radiotherapy) and control group: placebo as 2 capsules daily for 6 weeks. Main outcome measures: body weight, dietary intake,nutritional status, quality of life,serum CEA level, serum CRP,TNFα and IL-6 levels, serum Matrix Metalloproteinase-2 (MMP-2) and Matrix Metalloproteinase-9 (MMP- 9) levelsand side effects of treatment

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201503181197N18**
Registration date: **2015-06-14, 1394/03/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-14, 1394/03/24

Registrant information

Name
Reza Mahdavi
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Recruitment status

Recruitment complete

Funding source

Nutritional Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplementation on dietary intake, nutritional status, quality of life, serum matrix metalloproteinase, serum inflammatory factors(TNFα,IL-6) and side effect of treatments in rectal

patients undergoing neoadjuvant chemoradiotherapy

Public title
The effects of synbiotic supplementation on dietary intake،nutritional status, quality of life, serum Matrix Metalloproteinase enzymes,serum inflammatory markers levels(TNFα,IL-6) and side effects of treatment in rectal cancer patients undergoing neoadjuvant chemoradiotherapy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients with rectal cancer in stage 2 and 3 undergoing preoperative radiotherapy combined with chemotherapy. Exclusion criteria: clinically relevant pulmonary; cardiovascular; hepatic and kidney dysfunction; immunological disorders; pregnancy; lactation; ongoing or recent infections (within last 30 d); body mass index less than 18.5 ; treatment with anticoagulants; taking antibiotics in the last 3 week; usage of Probiotics or prebiotics or synbiotic and mineral supplements; intolerance of synbiotic supplement.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **46**
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
Tabriz University of Medical Sciences
City
Tabriz
Postal code

Approval date
2015-05-17, 1394/02/27
Ethics committee reference number
TBZMED.REC.1394.114

Health conditions studied

1

Description of health condition studied
Rectal cancer
ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

Primary outcomes

1

Description
Serum inflammatory factor TNFα, serum inflammatory factor IL-6
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
Immunoturbidimetry

Secondary outcomes

1

Description
Dietary intake
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
24 hour food recall and dietary record questionnaire

2

Description
Quality of life
Timepoint
Before radiotherapy and at the end of intervention(6 weeks)
Method of measurement
QLQ-30 questionnaire

3

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

4

Description
Added at 2016-02-28: side effects of treatment
Timepoint
Added at 2016-02-28: before radiotherapy and at the end of intervention
Method of measurement
Added at 2016-02-28: PG-SGA and WHO toxicity criteria questionnaire

Intervention groups

1

Description
Intervention group: Protexin synbiotic capsules (2 x 108 CFU Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium longum, Lactobacillus bulgaricus and fructooligosaccharide), 2 capsules a day for 6 weeks . The supplementation begins 1 week before starting radiotherapy to the end of radiotherapy.
Category
Prevention

2

Description
Control group: 2 placebo capsules a day for 6 weeks. The intervention begins 1 week before starting radiotherapy to the end of radiotherapy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Radiotherapy Department of Shahid Madany Hospital
Full name of responsible person
Dr. Mohammad Mohammadzadeh
Street address
Radiotherapy Department, Shahid Madany 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
Golgasht Street, Attar Neishaboori Avenue, Nutrition Research Center, Tabriz University of Medical Sciences 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
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Dr. Reza Mahdavi
Position
Ph.D in Nutrition
Other areas of specialty/work
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Person responsible for scientific inquiries

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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