

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of synbiotic supplementation on dietary intake, nutritional status, quality of life, serum matrix metalloproteinase, serum inflammatory factors(TNF α ,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(TNF α ,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,TNF α 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

Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

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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(TNF α ,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 (TNF α , 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 TNF α , 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

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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

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Position

Ph.D in Nutrition

Other areas of specialty/work

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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