

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Lactobacillus acidophil probiotic effects as an adjunctive therapy together standard drugs on side effects, treatment response and quality of life in patients with rectum cancer: Double Blind Randomized Clinical Trial

Protocol summary

Summary

Colorectal cancer is the third and the second most common cancer in the world and Iran, respectively. Scientists specialists suggested "Biological therapy" as a low cost and safe biological method for the treatment or the prevention of colorectal cancer. Our previous studies in animal colon cancer showed that the use of some probiotic strains such as Lactobacillus acidophilus in comparison with Bifidobacterium can reduce the incidence of cancer and tumor markers. In this present study randomized clinical trial phase 3, we aimed effects of Lactobacillus acidophil probiotic as adjuvant therapy in combination with standard therapies on treatment response and quality of life in colorectal patients. The subjects included 300 patients with rectum cancer in the Imam Khomeini hospital (Tehran University of Medical Sciences hospital) and Hazrat Rasoul Akram hospital (Iran University of Medical Sciences) from January 2015 to January 2016. Patients were randomly divided into two separate blocks of 150 patients including (i) Lactobacillus acidophilus probiotic capsules with standard therapy group and (ii) standard treatment without any probiotic. Patients in the first group will receive Lactobacillus acidophilus probiotic, capsules 2.5 mg daily (three times, before each meal) for at least 5 months before to two months after surgery and radiotherapy. Assessments including the quality of life improving, CT scans imaging and tumor marker examinations were operated during and the end of study to evaluate response to therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092118745N3**

Registration date: **2014-11-08, 1393/08/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name

Ali Mohammad Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

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+98 21 6119 2501

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aalizadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Iran University Of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Lactobacillus acidophil probiotic effects as an adjunctive

therapy together standard drugs on side effects, treatment response and quality of life in patients with rectum cancer: Double Blind Randomized Clinical Trial

Public title

Lactobacillus acidophil probiotic effects in rectum cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Randomized; with obtaining written consent; rectum cancer in neoadjuvant stage. Exclusion criteria: Patients with kidney problems or liver problems; patients with serious heart problems; patients with metastatic lung and brain cancer; patients with intestinal obstruction; patients with GFR less 30; patients with immunodeficiency.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **300**

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**

Tehran University of Medical Sciences

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Keshavarz Bulvar, Porsina Street

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Postal code

134511345

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

93/130/1195

Health conditions studied**1****Description of health condition studied**

Malignant neoplasms of digestive organs

ICD-10 code

C20-C21.2

ICD-10 code description

Malignant neoplasm of rectum, anus and anal canal whose point of origin cannot be classified to any one of the categories C20-C21.2

Primary outcomes**1****Description**

Response to treatment

Timepoint

Before and after drug therapy, 5 months

Method of measurement

CT scan

Secondary outcomes**1****Description**

The assesment of quality of life

Timepoint

Before and after of treatment, 5 months

Method of measurement

Questionnaires of FACT and CARES

Intervention groups**1****Description**

Patients will receive Lactobacillus acidophilus probiotic (capsules 500 mg, three times a day, before each meal) for at least 5 months before to two months after surgery and radiotherapy.

Category

Treatment - Drugs

2**Description**

Patients will receive the placebo capsules of Lactobacillus acidophilus probiotic (three times a day, before each meal) for at least 5 months before to two months after surgery and radiotherapy.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Iran

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Street address

Keshavarz Bulvar, Institut of Cancer

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Uonesian

Street address

Keshavarz Bulvar, Porsina Street.

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Tehran

Grant name

Grant code / Reference number

93-01-51-25308

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Position

Ph.D, Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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