Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Effects of Lactobacillus acidophilus probiotic as an adjuvant therapy with the standard treatments on the immune system and treatment efficacy in patients with locally advanced rectal cancer: Phase III randomized clinical trial

Protocol summary

Summary

Current study is aimed to investigate the effects Lactobacillus acidophilus as an adjuvant therapy with standard treatments, by improving the immune system function in patients with rectal cancer. 150 patients who will refer to Firoozgar and Imam Khomeini Hospital randomly from summer 95 to March 96. The patients will be block randomization divided into two 75-patient groups. The case group will receive Lactobacillus acidophilus capsule (1.5 g/daily, produced by Zist Takhmir Co), and the control group will receive the placebo capsules from one day before chemo-radiation to one week before surgery for 13 weeks. At the beginning and the end of study, answering to the questionnaire and related forms (CRF, FFQ), height and weight measurement and blood sampling will be performed by an expert person. Furthermore, at the end of 13th week, CT Imaging will be done on the patient for reinvestigation of tumor size under the clinical diagnosis. The tests carried out on serum samples include ELISA technique for evaluating the serum levels of cytokines, Real-time PCR for measuring the expression of STAT4 gene, and Flowcytometry for CDs measurement.

General information

Acronym

LA5 and CRC

IRCT registration information

IRCT registration number: **IRCT2016061118745N8**
Registration date: **2016-06-28, 1395/04/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-28, 1395/04/08

Registrant information

Name

Ali Mohammad Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6119 2501

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Seiences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Lactobacillus acidophilus probiotic as an adjuvant therapy with the standard treatments on the immune system and treatment efficacy in patients with locally advanced rectal cancer: Phase III randomized clinical trial

Public title

The effects of Lactobacillus acidophilus probiotic capsule administration on the immune system and treatment efficacy in patients with rectal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patient with locally advanced rectal cancer ; Patient with non-metastatic rectal cancer; Voluntary participation in the study and informed consent form fulfilling; Lack of swallowing disorder. Exclusion criteria : Patients with other cancers; Patients with renal and hepatic disorders; Patients with intestinal obstruction; Patients with low level of white blood cells (less than 1000 cells per mm3); Patients with drug intolerance or drug sensitivity to probiotics.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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 Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway,Iran University of Medical Sciences

City

Tehran

Postal code

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.IUMS.REC.1394/19753

Health conditions studied

1

Description of health condition studied

locally advanced rectal cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

Destroy of tumor or decrease of tumor size

Timepoint

The beginning and end of the study

Method of measurement

CT

Secondary outcomes

1

Description

STAT4 gene expression

Timepoint

The beginning and end of the study

Method of measurement

Real-time PCR

2

Description

the serum levels of cytokines

Timepoint

The beginning and end of the study

Method of measurement

ELISA technique

3

Description

CDs measurement

Timepoint

The beginning and end of the study

Method of measurement

Flowcytometry

Intervention groups

1

Description

Intervention group: The case group will receive Lactobacillus acidophilus capsule (1.5 g/daily, produced by Zist Takhmir Co) from one day before chemo-radiation to one week before surgery for 13 weeks.

Category

Treatment - Drugs

2

Description
Control group will receive the placebo capsules from one day before chemo-radiation to one week before surgery for 13 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Research Center, Cancer Institute of IR. Iran, Imam Khomeini Hospital
Full name of responsible person
Dr. Ali Mohammad Alizadeh
Street address
3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran
City
Tehran

2

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Dr. Farhad Zamani
Street address
Firoozgar Hospital, Behafarin St., Karimkhanzand St., Vali-E-Asr Sq.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Iran University of Medical Sciences
Full name of responsible person
Dr. Mousavi
Street address
Tehran, Hemmat Highway,Iran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Iran 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
Cancer Research Center, Cancer Institute of IR. Iran, Imam Khomeini Hospital
Full name of responsible person
Dr. Ali Mohammad Alizadeh
Position
Assistant Professor
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Person responsible for updating data

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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