

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The assessment of L-Lysine effect, as complementary treatment of chemical therapy, on biomarkers involved in patients with colorectal cancer and complications of chemical therapy

Protocol summary

Summary

Conventional chemotherapy after surgery for colorectal cancer can lead to numerous complications. Due to the natural structure of the L-Lysine amino acid, it has no side effects and also has ability of completion conventional chemotherapy treatment for colorectal cancer. This study is a randomized, double-blind, placebo-controlled, single-center trial. Patients with colorectal cancer who are undergone surgery will be divided in 2 groups of intervention and control, 50 individuals in each group. Serum bio-markers will be evaluated at the base line and 3 months after the treatment due to investigation on probable effect of L-Lysine on decreasing bio-markers level in comparison with conventional therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010612020N1**

Registration date: **2013-03-13, 1391/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-13, 1391/12/23

Registrant information

Name

Hosein Mirmiranpour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2358

Email address

miranpour.h@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Colorectal Resaerch Center, Rasoulakaram Hospital, Tehran University of Medical Sciences

Expected recruitment start date

2013-03-05, 1391/12/15

Expected recruitment end date

2014-03-06, 1392/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of L-Lysine effect, as complementary treatment of chemical therapy, on biomarkers involved in patients with colorectal cancer and complications of chemical therapy

Public title

The effect of L-Lysine on biomarkers involved in colorectal cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age between 20 to 70 years; 2- The existence of colorectal cancer - Duke B; 3- The operation of colon after colorectal cancer; 4- The first time achieving chemical therapy after colorectal cancer surgery. Exclusion criteria: 1- No desire to continue the contribution in investigation during the study; 2- side effects of therapy.

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: **50**

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

Street address

Tehran University of Medical Sciences, Enghelab st.

City

Tehran

Postal code**Approval date**

2012-12-09, 1391/09/19

Ethics committee reference number

90-03-30-18863

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

Colonl cancer

ICD-10 code

c18

ICD-10 code description

Malignant neoplasm of colon

2**Description of health condition studied**

Rectum cancer

ICD-10 code

c20

ICD-10 code description

Malignant neoplasm of rectum

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

ERCC1(Excision repair cross-complementing rodent repair deficiency, complementation group 1)

Timepoint

Baseline and 3 monhts following the end of treatment

Method of measurement

ELISA kit

2**Description**

VEGF(Vascular endothelial growth facto)

Timepoint

Baseline and 3 monhts following the end of treatment

Method of measurement

ELISA kit

3**Description**

DPD(Dihydropyrimidine dehydrogenase deficiency

Timepoint

Baseline and 3 monhts following the end of treatment

Method of measurement

ELISA kit

4**Description**

TS(Thymidylate synthase)

Timepoint

Baseline and 3 monhts following the end of treatment

Method of measurement

ELISA kit

5**Description**

CEA-Carcino Embryonic Antigen

Timepoint

Baseline and 3 monhts following the end of treatment

Method of measurement

ELISA kit

Secondary outcomes

empty

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

L-Lisyne powder 1.5g twice per day in combination with drugs of chemical therapy for patients in treatment group. The duration of treatment with L-lysin is 3 month.

Category

Treatment - Drugs

2

Description

In control group : placebo is powder as the same shape and color as L-lysine in combination with chemotherapy drugs ,twice a day foe 3 month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoulakaram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

4th Floor, Central building of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

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

Colorectal Resaerch Center, Rasoulakaram Hospital,Tehran University of Medical Sciences

Full name of responsible person

Hajar Nikbakht

Position

MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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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