

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation the effect of glutamine supplementation on inflammatory markers, surgical stress, carcinoembryonic antigen and postoperative outcomes in patients undergoing colorectal cancer surgery: a double-blind clinical trial study

Protocol summary

Study aim

To determine the effect of glutamine supplementation on inflammatory markers, surgical stress, carcinoembryonic antigen and postoperative outcomes in patients undergoing colorectal cancer surgery.

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, on 200 patients, with a convenient sampling method, and a table of numbers will be used for randomization.

Settings and conduct

This study will be conducted in patients with colorectal cancer who are candidates for elective surgery, among the patients referred to the colorectal surgery clinic in Sina Hospital in Tehran. One of the nurses will be responsible for random assignment patients and prescribing supplements for them. In order to carry out this research blindly, the supplements will be completely similar and closed in terms of appearance. Also, glutamine supplement and placebo are separated by a specific code from the company, which will be determined after analyzing the results of the code for each group. Researchers and doctors will not know about the studied groups and the type of supplement prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age \geq 18 years 2. American Society of Anesthesiologists (ASA) classification \leq III 3. Body mass index 18.5-30 4. Candidate for elective colorectal surgery Exclusion criteria: 1. Severe liver disorder 2. Kidney disorder

Intervention groups

Patients in the intervention group will receive glutamine powder 30 grams per day, and patients in the control group will receive a placebo with starch content for 10 days before surgery.

Main outcome variables

The ratio of neutrophils to lymphocytes, lymphocytes to monocytes, the concentration of C-reactive protein, carcinoembryonic antigen, and Interleukin, the incidence of postoperative complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200301046655N3**

Registration date: **2023-08-18, 1402/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-18, 1402/05/27**

Update count: **0**

Registration date

2023-08-18, 1402/05/27

Registrant information

Name

Razieh Khalooeifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8895 5975

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-27, 1402/05/05

Expected recruitment end date

2024-01-25, 1402/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of glutamine supplementation on inflammatory markers, surgical stress, carcinoembryonic antigen and postoperative outcomes in patients undergoing colorectal cancer surgery: a double-blind clinical trial study

Public title

Investigating the effect of glutamine in colorectal surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

American Society of Anesthesiologists (ASA) classification \leq III Body mass index 18.5-30 Candidate for elective colorectal surgery

Exclusion criteria:

Absence of severe hepatic impairment Absence of renal impairment

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **200****Randomization (investigator's opinion)**

Randomized

Randomization description

In this experiment, the balanced random block method will be used, with a block size of 4 (combination of A and B as groups). Using the Randomization.com website, random allocation will be done for 200 people in the form of 50 blocks of 4. Since body mass index is an important variable in the intervention effect. This intervention will be implemented in a classified manner. In order to carry out this trial correctly, a random allocation list will be produced separately for each of the two classes of body mass index 18.5 to 25 and 25 to 30.

Blinding (investigator's opinion)

Double blinded

Blinding description

One of the nurses will be responsible for randomly selecting patients and prescribing supplements for them. In order to carry out this research blindly, the supplements will be completely similar and closed in terms of appearance. Also, glutamine supplement and

placebo are separated by a specific code from the company, which will be determined after analyzing the results of the code for each group. Researchers and doctors will not know about the studied groups and the type of supplement prescribed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics committee of Sina Hospital

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.034

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

Colorectal cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

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

Carcinoembryonic antigen

Timepoint

At the beginning of the study (10 days before surgery), and one month after surgery

Method of measurement

Quantitative electroluminescence

Secondary outcomes

1

Description

Interleukin 6

Timepoint

At the beginning of the study (10 days before surgery), 12 hours before surgery and 48 hours after surgery

Method of measurement

Elisa method test

2

Description

Neutrophil to lymphocyte ratio

Timepoint

At the beginning of the study (10 days before surgery), 12 hours before surgery and 48 hours after surgery

Method of measurement

The ratio of blood neutrophils to blood lymphocytes

3

Description

Complications after surgery

Timepoint

During the first month after surgery

Method of measurement

Classification of complications based on Clavin-Dindo criteria

4

Description

Average ratio of lymphocytes to monocytes

Timepoint

At the beginning of the study (10 days before surgery), 12 hours before surgery and 48 hours after surgery

Method of measurement

The ratio of lymphocyte to monocyte

5

Description

reactive protein c

Timepoint

At the beginning of the study (10 days before surgery), 12 hours before surgery and 48 hours after surgery

Method of measurement

Immunoturbidometry method

Intervention groups

1

Description

Intervention group: They will receive glutamine powder (Karen Company) in the form of 30 grams per day for 10 days before surgery.

Category

Prevention

2

Description

Control group: They will receive placebo with starch content (Karen Company) for 10 days before surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Razieh Khalooeifard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Keshavarz Blvd., Qods Corner, Tehran University of Medical Sciences Headquarters

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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Razieh Khaloofard
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable