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 ≥ 18 years 2. American Society of Anesthesiologists (ASA) classification ≤ 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
Email address
shkhalooei1367@gmail.com

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 ≤ III Body mass index 18.5-30 Candidate for elective colorectal surgery
Exclusion criteria:
Absence of severe hepatic impairment Absence of renal impairment
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target 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
Street address
Imam Khomeini St, Hassan Abad Square
City
Tehran
Province
Tehran
Postal code
4691111367
Phone
+98 21 6634 8500
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+98 21 6634 8587
Email
hosp_sina@sina.tums.ac.ir
Web page address
https://sinahospital.tums.ac.ir/

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
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@sina.tums.ac.ir
Web page address
https://vcr.tums.ac.ir/
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 Khalooeifard

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Sina Hospital, Hassan Abad Square, Imam Khomeini St.

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11367 46911

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Razieh Khalooeifard

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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Position
Assistant Professor

Latest degree
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Other areas of specialty/work
Nutrition

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Web page address
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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