

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of high dose ascorbic acid on preventing anastomotic leakage after colon anastomosis surgery: a randomized clinical trial study

Protocol summary

Study aim

Determining the effect of high-dose ascorbic acid on anastomotic leakage after colon anastomosis surgery

Design

A clinical trial with a control group, with parallel groups, double-blind, on 88 patients, Randomized by the method of Balanced Block Randomization

Settings and conduct

This study is a double-blind randomized clinical trial, which is conducted in patients referred to independent educational-therapeutic centers of Qazvin province in 1402 who are candidates for colon anastomosis surgery according to the surgeon's order. 12 hours after the surgery for five days a single dose of vitamin C (1000mg) will be injected daily to a group and a placebo (distilled water) with the same volume will be injected to the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for colon anastomosis surgery; Age range 18-80 years Non-inclusion criteria: Patients with diabetes; Ischemic heart disease; Malnutrition (low nutritional standards including albumin<3.4 g/dl); Obese patients; Use of steroidal and non-steroidal anti-inflammatories; Immune system deficiency diseases; History of previous abdominal surgery; Emergency surgery; Patients undergoing chemotherapy; Taking any type of vitamin for at least the last three months; Allergy to vitamin C.

Intervention groups

The intervention group of 10 mg vitamin C is injected in a single dose (1000 mg) daily. The control group is injected with the same amount of distilled water.

Main outcome variables

Active secretions from the drain site, Recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059288N1**

Registration date: **2023-08-30, 1402/06/08**

Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**

Update count: **0**

Registration date

2023-08-30, 1402/06/08

Registrant information

Name

Farid Zare Ganjaroodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

faridz1991@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of high dose ascorbic acid on preventing anastomotic leakage after colon anastomosis surgery: a randomized clinical trial study

Public title

Investigating the effect of high dose vitamin C on preventing anastomotic leakage after colon anastomosis surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Colon anastomosis surgery candidate Age range 18-80

Exclusion criteria:

Having diabetes Heart ischemic disease Malnutrition (low nutritional standards, including albumin < 3.4 g/dl)

Obese patients Steroidal and non-steroidal anti-inflammatories consumption Pregnancy Patients undergoing chemotherapy History of previous abdominal surgery Immune system diseases Vitamin C allergy Taking any type of vitamin supplement at least 3 years ago

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation in this study is Balanced Block Randomization. 6 blocks AABB- ABAB_ ABBA- BBAA- BABA_ BAAB are numbered based on 1 to 6 and numbers 1 to 6 are selected from the table of random numbers and placed together. Then they are replaced with numbered blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

The surgical resident receives the drugs which are coded in closed envelopes and injects them into the patients. Coding is done by one of the colleagues of the project and the doctor, surgical resident, and patient are blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.QUMS.REC.1402.111

Health conditions studied

1

Description of health condition studied

Anastomotic leakage

ICD-10 code

K91.8

ICD-10 code description

Other intraoperative and postprocedural complications and disorders of digestive system

Primary outcomes

1

Description

Active secretions from the drain site

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

Clinical examination by a doctor

2

Description

Leukocytosis (More than 11,000 white blood cells in one microliter of blood)

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

CBC test

3

Description

Fistula (an abnormal passageway between adjacent organs or tissues or leading to the outside of the body)

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

Clinical examination by a doctor

4

Description

Malaise (disordered, weak and lethargic appearance, reduced alertness and lack of mastery and awareness of the surrounding environment and restlessness)

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

Clinical examination by a doctor

5

Description

Fever (body temperature 38 degrees Celsius or higher)

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

thermometer

6

Description

Recovery time (the number of days the patient is eligible to be discharged from the hospital)

Timepoint

From the time of the end of the surgery to ten days after that

Method of measurement

Clinical examination by a doctor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 10 mg of ascorbic acid with a concentration of 1000 as a single dose and daily starting 12 hours after colorectal anastomosis surgery for five days; product in the form of two ampoules of vitamin C with a concentration of 500 mg and a volume of 5 ml It is prepared from Osweh Pharmaceutical Company

Category

Prevention

2

Description

Control group: Injection of 10 mg of distilled water

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Farid Zare Ganjarody

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22 Bahman Blvd, Tavon Square, Elahiye Quay, Minodar Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahidi Mirhashemi

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researchdpt@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Farid Zare Ganjaroodi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

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

Analytic Code

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

Data Dictionary

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