

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Effect of vitamin C on inflammatory profile and circulatory shock in colon cancer patients undergoing colectomy in Imam Khomeini Hospital in Tehran 2023

#### Protocol summary

##### Study aim

Determining the effect of vitamin C on inflammatory profiles and circulatory shock in colon cancer patients undergoing colectomy

##### Design

Clinical trial with two parallel group randomized, double-blind, design on 42 patients, "Random software allocation" software was used for randomization.

##### Settings and conduct

Study related to patients with colon cancer, for elective laparotomy colectomy in Imam Khomeini hospital complex in Tehran. It is a double-blind type, where the participants and the outcome assessor are unaware. In the intervention group, receive vitamin C and their inflammatory factors are measured compared to control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include patients over 20 years of age undergoing elective colon cancer surgery for the first time, who are admitted to the intensive care unit with post-operative shock. Exclusion criteria: sepsis before surgery, myocardial ischemia in recent hospitalization (positive troponin test on two times), acute kidney injury (creatinine increase 1.5 times the baseline creatinine level), immunotherapy before surgery, oxalate kidney stones (urinalysis), G6PD enzyme deficiency, immunotherapy before surgery, history of corticosteroid use, rheumatic disease, morbid obesity (BMI $\geq$ 40), concurrent cancers in other organs or having cancer with metastasis and previous colon cancer surgery.

##### Intervention groups

In the intervention group, vitamin C (Elixir, Iran) in 0.9% normal saline (Qazi, Iran) with a dose of 6 grams per day (1.5 g every 6 hours) was added to a volume of 50 ml through a syringe pump during injected to peripheral or central vessels in 30 minutes. It is prescribed for 5 days. Patients in the control group were given a placebo (0.9%

normal saline) at the same time and number of times.

##### Main outcome variables

Function of organs and inflammatory factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120216009045N5**

Registration date: **2023-02-19, 1401/11/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-02-19, 1401/11/30**

Update count: **0**

##### Registration date

2023-02-19, 1401/11/30

##### Registrant information

##### Name

Mohammad Taghi Beigmohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2511

##### Email address

beigmohammadi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-22, 1401/10/01

##### Expected recruitment end date

2023-06-21, 1402/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of vitamin C on inflammatory profile and circulatory shock in colon cancer patients undergoing colectomy in Imam Khomeini Hospital in Tehran 2023

**Public title**

The effect of vitamin C in shock

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients over 20 years old Undergoing elective colon cancer surgery for the first time Following the postoperative shock, they are immediately admitted to the ICU

**Exclusion criteria:**

Sepsis before surgery Myocardial ischemia in a recent hospitalization (positive troponin test on two time) Acute kidney injury (creatinine increase 1.5 times the baseline creatinine level) Immunotherapy before surgery oxalate kidney stones G6PD enzyme deficiency History of rheumatic disease History of corticosteroid use History of rheumatic disease Morbid obesity (BMI  $\geq$ 40) Simultaneous cancers in other organs metastatic cancer Previous colon cancer surgery

**Age**

From **20 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The simple randomization method is in the form of a letter. In this method, a number of cards or letters chosen by the researcher are considered as the first group and the same number of cards for the next groups it is possible. By merging the cards together, one card is issued and its allocation is recorded, and that card is returned to the group of other cards after being issued. The cards are merged again and another card is removed. This process continues until reaching a random sequence according to the sample size. Stratified randomization is used in studies with small sample size. Based on simple randomization, they are able to produce random sequence by block method, including "Random software allocation" software. The method of concealment of random allocation is the use of sealed and waxed opaque envelopes in a random sequence. According to the sample size of the research is a number

of envelopes with aluminum foil (due to the lack of clarity of the content envelopes), preparation and each of the created random sequences is recorded on a card and the cards are placed in the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order. At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the letter envelopes was opened in order and its assigned group was found. The participant is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double-blind type, which means that both the study participants and the patient outcome assessor will not know about the type of interventions. The intervention under study and the placebo will be completely similar in terms of color, size and smell. Except for the main researcher of the study, who has the role of the project leader and has no role in selecting patients, choosing interventions, prescribing interventions, evaluating the outcome of patients, he will know the type of interventions assigned to patients, finally none of the participants and evaluating researchers. Outcome Patients will not know the type of interventions received until the end of the study. The data analyst also does not know the type of intervention and control groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

**Street address**

Imam Khomeini Hospital Complex, Dr. Gharib Ave., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2023-01-08, 1401/10/18

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1401.271

## Health conditions studied

1

### Description of health condition studied

Hemodynamic Shock

### ICD-10 code

R57.9

### ICD-10 code description

Shock, unspecified

## Primary outcomes

1

### Description

Inflammatory factors ( IL-6, CRP, Lactate, ESR)

### Timepoint

At the beginning of the study and then daily for 5 days

### Method of measurement

Laboratory examination of blood samples

## Secondary outcomes

1

### Description

Length of hospitalization

### Timepoint

From the beginning of the study until discharge or death

### Method of measurement

Daily checking of the variables by the researcher

2

### Description

Duration of hospitalization in the intensive care unit

### Timepoint

From the beginning of the study on a daily basis until discharge or death from the intensive care unit

### Method of measurement

Number of days assessed by the researcher

## Intervention groups

1

### Description

Intervention group: Vitamin C (Elixir, Iran)1.5 g every 6 hours in 0.9% normal saline (Qazi, Iran) was added to a volume of 50 ml through a syringe pump within 30 minutes. It is injected into peripheral or central vessels. This prescription is given for 5 days.

### Category

Treatment - Drugs

2

### Description

Control group: Normal saline 0.9% (Qazi, Iran) is reached to a volume of 50 ml and is injected into peripheral or central vessels through a syringe pump in a period of 30

minutes. This prescription is given for 5 days.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Khomeini Hospital Complex

#### Full name of responsible person

Mohammad Taghi Beig Mohammadi

#### Street address

Imam Khomeini Hospital Complex, Dr. Gharib Ave., Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۱۹۷۳۳۱۴۱

#### Phone

+98 21 6119 0000

#### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Ahmadi

#### Street address

Imam Khomeini Hospital Complex, Dr. Gharib Ave., Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

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#### Phone

+98 21 6119 0000

#### Email

Imamhospital@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**

Mohammad Taghi Beig Mohammadi

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Hospital Complex, Dr. Gharib Ave.,  
Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 6119 0000

**Email**

mbage46@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Taghi Beig Mohammadi

**Position**

Professor

**Latest degree**

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mbage46@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Phone**

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**Email**

mbage46@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared after de-identification of subjects  
and termination of the study.

**When the data will become available and for how long**

Access starts one year after the end of the study and  
publication of the results

**To whom data/document is available**

Researchers working in academic and scientific  
institutions

**Under which criteria data/document could be used**

They will be allowed to use the documents to carry out  
research projects without changing the data analysis.

**From where data/document is obtainable**

Imam Khomeini Hospital Complex, Dr. Gharib Ave,  
Keshavarz Blvd., Tehran. Postal code: 1419733141 Dr.  
Mohammad Taghi Beig Mohammadi Contact number  
:0098911759016 Email address: mbage46@gmail.com

**What processes are involved for a request to access**

**data/document**

Face-to-face communication, phone calls, and email addresses are available and will be answered as soon as

possible if eligible.

**Comments**