

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of vitamin C administration on the Consumption of blood products in patients undergoing open heart surgery in two groups of tranexamine and vitC+tranexamine (randomized clinical trial)

#### Protocol summary

##### Study aim

The effect of vitamin C on the Consumption of blood products in patients undergoing open heart surgery

##### Design

clinical trial with control group, Double-blind, randomized phase 2 on 120 cardiac surgery patients computer randomization table was used.

##### Settings and conduct

The place of study is Sayyad Shirazi Medical Education Center, Gorgan. Patients will have informed consent. This study is double-blind, the patient and the patient assessor will not know the type of intervention, and only the specialist responsible for the injection will know about the drug content based on the code inserted on the serum.

##### Participants/Inclusion and exclusion criteria

Entry criteria: age 30 to 80 years, EF more than 30%, first heart surgery, written informed consent, no history of drug sensitivity, Absence of coagulation disorder  
Exclusion criteria: Non-cooperation to continue participating in the study

##### Intervention groups

Tranexamic acid intravenous alone and combined  
Tranexamic acid with vitamin C

##### Main outcome variables

Measurement of blood loss during and after surgery;  
Measuring the use of blood products (cell packs, platelets, fresh frozen blood, etc.) during and after surgery;  
Measurement of hemoglobin drop rate after surgery;  
Measurement of length of stay in ICU and hospital

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230607058400N1**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

##### Registration date

2023-06-13, 1402/03/23

##### Registrant information

###### Name

sina mohajernoiei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3255 8012

###### Email address

mohajernoiei@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-22, 1402/04/01

##### Expected recruitment end date

2024-06-21, 1403/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of vitamin C administration on the Consumption of blood products in patients undergoing open heart surgery in two groups of tranexamine and

vitC+tranexamine (randomized clinical trial)

### Public title

The effect of vitamin C administration on the Consumption of blood products in patients undergoing open heart surgery in two groups of tranexamine and vitC+tranexamine (randomized clinical trial)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age between 30-80 years EF>30% BMI<26 written informed consent no history of drug sensitivity first heart surgery no history of disorders and coagulation factors hemoglobin more than 10 gr/dl

#### Exclusion criteria:

Dissatisfaction and willingness to participate in the study

### Age

From **30 years** old to **80 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization is done through random blocks of four, the unit of randomization will be individual (each patient), random assignment of patients to groups is done in the order of permutations of generated random blocks. For this study, For this study, 15 blocks of 4 will be produced using the software, so that in each block, two members from group one and two members from group two are considered.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Patients do not know their treatment group, and the medical personnel and the patient evaluator will not know the type of drug, and only the specialist responsible for the injection based on the code inserted on the serum will know about its content. In this study, the outcome assessor and the data analyst also do not know the type of study

### Placebo

Not used

### Assignment

Parallel

### Other design features

There is no unique specification

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

##### Street address

International Medical Faculty, Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd

##### City

Gorgan

##### Province

Golestan

##### Postal code

7451549341

#### Approval date

2023-04-25, 1402/02/05

#### Ethics committee reference number

IR.GOUMS.REC.1402.060

## Health conditions studied

### 1

#### Description of health condition studied

Haemorrhagic condition in open heart surgery

#### ICD-10 code

D69.9

#### ICD-10 code description

Hemorrhagic condition, unspecified

## Primary outcomes

### 1

#### Description

Measurement of blood loss during and after surgery

#### Timepoint

at Hour 0, 2, 4, 6, 8, 10, 12

#### Method of measurement

visual estimation of blood loss in bottles

## Secondary outcomes

### 1

#### Description

Measuring length of stay in ICU

#### Timepoint

Days of hospitalization in the ICU

#### Method of measurement

number of days

**2****Description**

Measuring length of stay in hospital

**Timepoint**

Days of hospitalization in hospital

**Method of measurement**

number of days

**3****Description**

Measuring the amount of hemoglobin drop

**Timepoint**

after surgery

**Method of measurement**

blood test

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

Intervention group: transamine injection alone 50Mg/kg bolus before surgical incision (Iran. Co Pharmaceutical Tamin Caspian®, Tranexip ) Half an hour before the surgery, the patient will be infused with 2 grams of vitamin C ampoule along with 100 cc of normal saline serum (Daroupakhsh Factory-Iran-Tehran) and then 1000 mg of vitamin C will be given every day for the first 4 days.

**Category**

Treatment - Drugs

**2****Description**

Control group: transamine injection alone 50Mg/kg bolus before surgical incision (Iran. Co Pharmaceutical Tamin Caspian®, Tranexip )

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sayyad Shirazi Medical Education Center

**Full name of responsible person**

Fozieh Bakhsha

**Street address**

Sayyad Shirazi Blvd

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917867439

**Phone**

+98 17 3220 2154

**Email****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Narges Beigom Mirbehbahani

**Street address**

Vice Chancellor for research of Medical Sciences, Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd

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n.mirbehbahani@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gorgan 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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Fozieh Bakhsha

**Position**

instructor faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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instructor faculty member  
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## Person responsible for updating data

### Contact

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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