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 mohajernoei
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 17 3255 8012
Email address
mohajernoei@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 conten sot 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
infosayyad@goums.ac.ir

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
City
Gorgan
Province
Golestan
Postal code
7451549341
Phone
+98 17 3242 3630
Email
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
Street address
Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd
City
Gorgan

Province
Golestan
Postal code
7451549341
Phone
+98 17 3245 0663
Email
bakhsha_fo@yahoo.com

Person responsible for scientific 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
Street address
Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd
City
Gorgan
Province
Golestan
Postal code
7451549341
Phone
+98 17 3245 0663
Email
bakhsha_fo@yahoo.com

Person responsible for updating data

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
Street address
Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd
City
Gorgan
Province
Golestan
Postal code
4934174515
Phone
+98 17 3245 0663
Email
bakhsha_fo@yahoo.com

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