

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy and investigating clinical outcomes in the intensive care unit: a randomized double-blind study

Protocol summary

Study aim

Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy

Design

En Clinical trial with 3 groups, with parallel groups, double blind, randomized, phase 3 on 105 patients. For randomization, a simple randomization method is used using a table of random numbers.

Settings and conduct

After the ethics committee's approval and obtaining the patient's consent, 105 candidates for radical cystectomy in modarres Hospital who meet the criteria as mentioned above will be included in the study. Patients are assigned to one of the 3 groups by simple randomization method. Individuals responsible for randomization from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

Participants/Inclusion and exclusion criteria

Patients who are candidates for elective radical cystectomy surgery under general anesthesia with muscle relaxation and mechanical ventilation without a history of anticoagulant therapy, blood abnormality or coagulopathy, chronic liver disease, chronic kidney disease with a serum creatinine level of > 2 mg/dL, preoperative plasma fibrinogen level of ≤ 150 or ≥ 400 mg/dL or history of heart infarction, deep vein thrombosis, pulmonary embolism, stroke

Intervention groups

After general anesthesia, patients are assigned to one of 3 groups that receive 2 grams of fibrinogen, or 15 mg/kg of tranexamic acid, or a combination of both as 5 mg/kg of tranexamic acid and one gram of fibrinogen intravenously.

Main outcome variables

Intraoperative hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230204057318N4**

Registration date: **2023-11-28, 1402/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-28, 1402/09/07**

Update count: **0**

Registration date

2023-11-28, 1402/09/07

Registrant information

Name

Alireza Shakeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

dr.alirezashakeri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of prophylactic administration of fibrinogen, tranexamic acid, or simultaneous use of both on perioperative bleeding in patients undergoing radical cystectomy and investigating clinical outcomes in the intensive care unit: a randomized double-blind study

Public title
Comparing the effect of prophylactic administration of fibrinogen and tranexamic acid in radical radical cystectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for elective radical cystectomy surgery under general anesthesia with muscle relaxation and mechanical ventilation

Exclusion criteria:

Patient on anticoagulant agent Having a known blood Abnormality or coagulopathy Chronic liver disease Chronic kidney disease with a serum creatinine level of > 2 mg/dL Preoperative plasma fibrinogen level of ≤150 or ≥ 400 mg/dL History of heart infarction, deep vein thrombosis, pulmonary embolism, stroke

Age
From **40 years** old to **80 years** old

Gender
Male

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, a simple randomization method was used using a table of random numbers and through the Random generator program of the Android version. In this randomization, patients who meet the criteria for entering the study are assigned a number before anesthesia, which will represent one of the three study groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the fact that the patients are unaware of the drug content, they are blinded to their group. Also, the drugs were prepared by a person outside the study group and

the treatment group of patients with numbers, so the treatment group is also unaware of the colorless drug. Also, the people who perform the investigations of intraoperative bleeding and other postoperative outcomes are also blinded to the patient group. The data analyst will not know about the coding of the groups.

Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Yaman st., Shahid Chamran Hwy.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.415

Health conditions studied

1

Description of health condition studied

Intraoperative radical cystectomy

ICD-10 code

I97.42

ICD-10 code description

Intraoperative hemorrhage and hematoma of a circulatory system organ or structure complicating other procedure

Primary outcomes

1

Description

Intraoperative hemorrhage

Timepoint

Intraoperative

Method of measurement

Measuring of the suction bottle and bloody gauze and hemoglobin level

Secondary outcomes

1

Description

Hospitalization days

Timepoint

Postoperative period

Method of measurement

days

2

Description

ICU length of stay

Timepoint

Postoperative period

Method of measurement

Days

3

Description

Arterial blood gas

Timepoint

Intraoperative

Method of measurement

Arterial blood sampling

4

Description

Morbidity (Pneumonia, wound infection, postoperative bleeding, Deep vein thrombosis, pulmonary thromboembolism, Stroke, Myocardial infarction)

Timepoint

Postoperative

Method of measurement

Patient file

5

Description

Packed red blood cells transfusion amount

Timepoint

perioperative

Method of measurement

Milliliters

Intervention groups

1

Description

Intervention group: After general anesthesia, patients in the fibrinogen group will be administered two grams of fibrinogen intravenously dissolved in 100 ml of distilled water.

Category

Treatment - Drugs

2

Description

Intervention group: After general anesthesia, patients in the tranexamic acid group will be administered 15 mg/kg of tranexamic acid intravenously dissolved in 100 ml of distilled water.

Category

Treatment - Drugs

3

Description

Intervention group: After general anesthesia, patients in the mixed group will be administered 5 mg/kg of tranexamic acid and 1g of fibrinogen intravenously dissolved in 100 ml of distilled water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Maede Karimian

Street address

Modarres Hospital, Saadat Abad intersection, Yadgar Imam highway

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Tehran

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1998734383

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Fax

Email

pr_modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran

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1983963113

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zarghi@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Shakeri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Email

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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 more 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

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