

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Prophylactic Fibrinogen effect on perioperative bleeding in radical cystectomy: a double-blind randomized placebo-controlled study

Protocol summary

Study aim

In this study we will assess whether the prophylactic fibrinogen administration before radical cystectomy would decrease bleeding during surgery or not

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

All patients are blinded and anesthesiologist will only know who had received fibrinogen

Participants/Inclusion and exclusion criteria

All patients with bladder cancer who are candidates for elective radical cystectomy are included exclusion criteria are: Anticoagulant agent Having a known blood Abnormality or coagulopathy A history of thromboembolism Chronic liver disease Chronic kidney disease A preoperative plasma fibrinogen level of ≥ 400 mg/dl Intake of non-steroidal anti-inflammatory drugs within 2 days prior to surgery

Intervention groups

Patients in study group will receive 2 grams of fibrinogen and in control group will receive 100 cc normal saline

Main outcome variables

amount of bleeding during surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045091N1**

Registration date: **2020-01-30, 1398/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-30, 1398/11/10**

Update count: **0**

Registration date

2020-01-30, 1398/11/10

Registrant information

Name

Mohsen Arian nik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4447 7493

Email address

m.ariannik@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-15, 1398/09/24

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic Fibrinogen effect on perioperative bleeding in radical cystectomy: a double-blind randomized placebo-controlled study

Public title

Prophylactic Fibrinogen and perioperative bleeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients older than 18 years old Admitted for elective radical cystectomy localized bladder cancer (T1-2N0M0)

Exclusion criteria:

Anticoagulant agent Having a known blood Abnormality or coagulopathy (abnormal values of platelet count, PT,

APTT, fibrinogen, antithrombin, or Ddimer) A history of thromboembolism Chronic liver disease Chronic kidney disease with a serum creatinine level of > 2 mg/dl A preoperative plasma fibrinogen level of $\geq$ 400 mg/dl intake of non-steroidal anti-inflammatory drugs within 2 days prior to surgery

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Random Sampling using table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

the study group will receive 2 grams of fibrinogen in 100 cc of distilled water by an anesthetist 30 min before surgery and control group will receive the same amount of normal saline, the anesthesiologist will know only the patients who had received fibrinogen

Placebo

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

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.033

Health conditions studied**1****Description of health condition studied**

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

ICD-10 code

N99.61

ICD-10 code description

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

2**Description of health condition studied**

Acquired absence of other parts of urinary tract

ICD-10 code

Z90.6

ICD-10 code description

Acquired absence of other parts of urinary tract

3**Description of health condition studied**

Malignant neoplasm of bladder, unspecified

ICD-10 code

C67.9

ICD-10 code description

Malignant neoplasm of bladder, unspecified

Primary outcomes**1****Description**

Blood loss during surgery

Timepoint

at the end of surgery

Method of measurement

visual evaluation

Secondary outcomes

empty

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

Intervention group: receive 2 grams of fibrinogen in 100 cc distilled water

Category

Prevention

2

Description

Control group: receive 100 cc normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Educational hospital

Full name of responsible person

Mohsen Arian Nik

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Saadat Abad St. Yadegare Imam Highway

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Web page address

<http://www.sbmu.ac.ir/index.jsp?fkeyid=&siteid=102&pageid=12851>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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5th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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

Mohsen Arian nik

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

Resident

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Person responsible for updating data

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all data sets will be shared

When the data will become available and for how long

6 months after publication

To whom data/document is available

available for people working in academic institutions

Under which criteria data/document could be used

no criteria

From where data/document is obtainable

m.ariannik@sbmu.ac.ir

What processes are involved for a request to access data/document

proof of academic

Comments