Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Assessing the efficacy of Tranexamic acid versus placebo in reducing fibrinolysis, blood loss, and transfusion requirements during open prostatectomy surgery

Protocol summary

Study aim

Assessing the effect of tranexamic acid on reducing fibrinolysis, bleeding and the need for blood transfusion in open prostatectomy

Design

This is a two-arm, parallel-group, double-blind, randomized trial. A total of 40 patients who are undergoing open prostatectomy with spinal anesthesia is recruited. Study participants are randomized to receive either tranexamic acid (10mg/kg) or normal saline solution (100cc) over 30 minutes before initiation of surgery using a randomization table. Estimated blood loss and the need for blood transfusion are recorded. Two venous blood samples (5cc) are obtained from each patient (at the beginning and at the end of the operation) to perform rotational thromboelastometry (ROTEM) analysis.

Settings and conduct

This double-blinded study is performed in Sina Hospital, Tehran, Iran. The anesthesiologist (main researcher) and patients are blinded to study allocation.

Participants/Inclusion and exclusion criteria

Male patients who are undergoing open prostatectomy exclusion criteria: use of anticoagulant or anti-platelet medications, known history of coagulopathy, previous history of DVT or PTE

Intervention groups

Intervention group: patients receive tranexamic acid (10mg/kg) diluted in 100cc of normal saline solution over 30 minutes before initiation of surgery placebo group: patients only receive 100cc of normal saline over 30 minutes before initiation of surgery

Main outcome variables

blood loss volume; blood transfusion; fibrinolysis in rotational thromboelastometry analysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170805035510N6**
Registration date: **2019-09-17, 1398/06/26**
Registration timing: **prospective**

Last update: **2019-09-17, 1398/06/26**
Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

Pejman Pourfakhr

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4466 3963

Email address

pourfakhr@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing the efficacy of Tranexamic acid versus placebo in reducing fibrinolysis, blood loss, and transfusion requirements during open prostatectomy surgery

Public title
Application of Tranexamic acid in prostatectomy surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are undergoing open prostatectomy surgery with spinal anesthesia
Exclusion criteria:
Administration of general anesthesia (patients who do not consent for spinal anesthesia or failure of spinal anesthesia) Previous history of deep vein thrombosis, pulmonary emboli or myocardial infarction Patients who receive packed red blood cells within one week of surgery Hemoglobin level lower than 10 mg/dl Use of anticoagulant drugs (Warfarin, Heparin, etc) within one month of surgery Use of antiplatete medications (Clopidogrel, Aspirin, etc) within one month of surgery Previous diagnosis of coagulopathy Patients who are assigned to the American Society of Anesthesiologists physical status classification of III or higher
Age
No age limit
Gender
Male

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed by employing the simple randomization method and random number table. Patients are allocated into two groups (20 patients in each group).
Blinding (investigator's opinion)
Double blinded
Blinding description
The main researcher (anesthesiologist) and the patients are unaware of study allocation. A nurse anesthetist (who is not involved in the study) receives the randomization table in a sealed envelope and allocates patients to study group according to the table. Rotational thromboelastometry (ROTEM) analyses are performed by the anesthesiologist and obtained data are entered into Statistical Package for the Social Sciences (SPSS) software. All the clinical assessments, including blood loss estimation and adminstiring packed red blood cells are performed by the main researcher who is blinded to study 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 and Health services
Street address
Tehran University of Medical Sciences, Central Building, Ghods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-07-25, 1397/05/03
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.287

Health conditions studied

1

Description of health condition studied
Fibrinolysis and bleeding during open prostatectomy
ICD-10 code
T81.0
ICD-10 code description
Haemorrhage and haematoma complicating a procedure, not elsewhere classified

Primary outcomes

1

Description
intraoperative blood loss
Timepoint
At the end of surgery
Method of measurement
The volume of blood absorbed by surgical gauze was estimated using Gauze Visual Analogue method. The mentioned figures plus the amount of blood in the surgical suction pump was considered as the total amount of intraoperative blood loss

2

Description
transfusion of packed red blood cell
Timepoint
During the surgery
Method of measurement
the number of transfused PC were recorded

Secondary outcomes

1

Description
fibrinolysis (based on rotational thromboelastometry analysis)
Timepoint
before intervention and at the end of surgery
Method of measurement
rotational thromboelastometry (ROTEM)

Intervention groups

1

Description
Intervention group: Patients receive tranexamic acid (10mg/kg) diluted in normal saline (100cc) over 30 minutes before initiation of surgery
Category
Treatment - Drugs

2

Description
Control group: patients receive normal saline (100cc) over 30 minutes before initiation of surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Pejman Pourfakhr
Street address
Sina hospital, Imam Khomeini street
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir
Web page address
http://en.sinaih.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
msahrai@sina.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
Pejman Pourfakhr
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Province
Tehran

Postal code
1848836578
Phone
+98 21 4466 3963
Fax
+98 21 4466 3963
Email
pourfakhr@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Pejman Pourfakhr
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1848836578
Phone
+98 21 4466 3963
Fax
+98 21 4466 3963
Email
pourfakhr@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamadreza Neishaboury
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1848836578
Phone
+98 21 4427 2306
Email
m.neishaboury@gmail.com

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
Considering the limited number of open prostatectomies which are performed in our hospital, there is a concern regarding our participants' privacy and whether were are able to maintain patients' anonymity.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available