# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Effectiveness of topical Tranexamic Acid for reducing bleeding in prostate surgeries

## Protocol summary

**Study aim**
Effectiveness of topical Tranexamic Acid for reducing bleeding in prostate surgeries
**Design**
This study is clinical trial and double blind.93 patients candidate for prostate surgery in Valiasr Hospital in Arak will inter this study.We will divide patients in 3 groups by simple randomization.Groups are parallel.
**Settings and conduct**
This study is clinical trial and double blind.93 patients candidate for prostate surgery in Valiasr Hospital in Arak will inter this study.Outcome assessor and analyzer don't aware from grouping.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria:Ages over 18 years, ASA class 1 and 2, prostate weight less than 150 gram, hemoglobin greater than or equal to 10, body mass index less than 35
Exclusion criteria: Coagulopathy, history of prostate cancer, addiction to opioids, pre-surgical Finasteride treatment history, history of atrial fibrillation and coronary artery disease, thrombophilia, dissatisfaction
**Intervention groups**
Group 1: Tranexamic Acid (Iran-Rasht Caspian Vial Pharmaceutical Company 0.5 x 5 ml) was administered according to the following protocol: 20 minutes before surgery 15 milligram in kilogram Tranexamic acid body weight (Diluted with 100 milliliter of normal saline) was slowly infused over a period of 20 minutes as an intravenous infusion. Group II:  Patients are given 1 gram oral Tranexamic acid (Made in Iran - 250 milligram Amin Capsule Pharmaceuticals) 30 minute before surgery. Group III: 1 g is poured into 10 milliliter and poured topically (Made in Iran-Rasht Caspian Pharmaceutical Company) at the surgical site.
**Main outcome variables**
Bleeding rate, surgeon satisfaction

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20141209020258N134**
Registration date: **2020-03-05, 1398/12/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-05, 1398/12/15**
Update count: **0**
**Registration date**
2020-03-05, 1398/12/15

**Registrant information**
**Name**
Fariba Farokhi
**Name of organization / entity**
Arak University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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+98 86 3222 2003
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2019-09-09, 1398/06/18
**Expected recruitment end date**
2020-03-19, 1398/12/29
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effectiveness of topical Tranexamic Acid for reducing bleeding in prostate surgeries

**Public title**
Effectiveness of topical Tranexamic Acid for reducing bleeding in prostate surgeries
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Ages over 18 years ASA class 1 and 2 Prostate weight less than 150 gram Hemoglobin greater than or equal to 10 Body mass index less than 35
**Exclusion criteria:**
Coagulopathy History of prostate cancer Addiction to Opioids Pre-surgical Finasteride treatment history A history of atrial fibrillation and coronary artery disease Thrombophilia Dissatisfaction
**Age**
From **18 years** old
**Gender**
Male

**Phase**
2
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **93**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple individual randomization with randomization with envelopes in two groups A and B and C. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B and C are available to analyzer and outcome assessor.Group A received placebo infusion and group B received serum infusion tablets.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics comittee of Arak University of Medical Sciences
**Street address**
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Approval date**
2019-09-08, 1398/06/17
**Ethics committee reference number**
IR.ARAKMU.REC.1398.166

## Health conditions studied

### 1

**Description of health condition studied**
Prostate surgery
**ICD-10 code**
D29.1
**ICD-10 code description**
Benign neoplasm of prostate

## Primary outcomes

### 1

**Description**
Bleeding rate
**Timepoint**
During surgery
**Method of measurement**
Observation

### 2

**Description**
Surgeon satisfaction
**Timepoint**
During surgery
**Method of measurement**
Observation

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: Tranexamic Acid (Iran-Rasht Caspian Vial Pharmaceutical Company 0.5 x 5 ml) was administered according to the following protocol: 20 minutes before surgery 15 milligram in kilogram Tranexamic acid body weight (Diluted with 100 milliliter of normal saline) was slowly infused over a period of 20 minutes as an intravenous infusion.They are given a placebo to blindly receive a tablet similar to the tranexamic acid pill.

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: Patients are given 1 gram oral Tranexamic acid (Made in Iran - 250 milligram Amin Capsule Pharmaceuticals) 30 minute before surgery.Serum is also given to patients for blindness.

**Category**
Treatment - Drugs

### 3

**Description**
Intervention group 3: 1 gram Tranexamic acid is poured into 10 milliliter and poured topically (Made in Iran-Rasht Caspian Pharmaceutical Company) at the surgical site.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Valiasr Hospital

**Full name of responsible person**
Dr Afsaneh Norouzi

**Street address**
Valiasr hospital, Valiasr squre

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3814957558

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Nourozi@arakmu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
Dr Alireza Kamali

**Street address**
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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alikamaliir@yahoo.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Arak 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**
Arak University of Medical Sciences

**Full name of responsible person**
Dr Behnam Mahmodie

**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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Arak University of Medical Sciences

**Full name of responsible person**

Dr Amirali Bahreyni

**Position**

Resident of anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

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amialibahreyni@yahoo.com

**Web page address**

## 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

Researcher in university

**Under which criteria data/document could be used**

If there are additional questions

**From where data/document is obtainable**

Dr Norouzi

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

They have to write letters to the professors and the university

**Comments**