

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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 enter 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 enter 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)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

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 committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, 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 square

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikalaliir@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 square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Afsaneh Noruzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3471 3638

Fax

Email

dr.noruzi@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

Anesthesiology

Street address

Payambar Azam Complex, Basij Square, Sardasht,

Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

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