

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of topical tranexamic acid in control of lower urinary system bleeding in emergency department

Protocol summary

Summary

The purpose of this study is to evaluate the effects of topical Tranexamic acid in control of lower urinary tract bleeding. 50 Patients older than 40 years old with gross hematuria will be included in this study who referred to emergency department of Imam Reza (AS) Hospital, Tabriz. Exclusion criteria include pregnancy, lactation, history of thrombosis or thromboembolism, coagulopathy, history of myocardial infarction or ischemic stroke, renal failure, urinary tract infarction, and disagreement to contribute to the research. In these patients, bladder will be irrigate with 1 liter of Normal Saline 0.9% serum first, then patients will be divided into 2 groups randomly. For intervention group, 500 mg Tranexamic acid in 500cc Normal Saline 0.9% will be administered via 3 branch Foley catheter. For control group, 10 cc pure water in 500 cc normal saline 0.9% will be used for bladder irrigation as placebo. Tranexamic acid & pure water were prepared in different 10 cc syringes by researcher that both of physician & patient are unaware about them. Then all patients will be admitted to urology ward for 24 hours. Amount of hematuria will be checked by urinary test tape before intervention, 1, 3, 6, and 24 hours after intervention. Also, we will check hemoglobin level at arrival time, 6, and 24 hours after it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072118545N1**
Registration date: **2015-02-25, 1393/12/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-25, 1393/12/06

Registrant information

Name

Seyed Hossein Ojaghi Haghighi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 2078

Email address

haghighis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-19, 1393/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical tranexamic acid in control of lower urinary system bleeding in emergency department

Public title

Effect of topical tranexamic acid in control of urinary bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : (patient over 40 years old; lower urinary system bleeding like clot or fresh blood).

Exclusion criteria : (pregnancy; lactation; history of thrombosis or thromboemboli; coagulopathy; history of myocardial infarction or ischemic stroke; renal failure; urinary tract infarction; disagreement to contribute to research)

Age

From **40 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization of study will done with computerize program and patient will divided to group 1 and 2. Every group has 25 patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Vice Chancellor for Research of Tabriz University of Medical Sciences

Street address

Golgasht avenue, Tabriz university medical science

City

Tabriz

Postal code

5166614756

Approval date

2014-05-05, 1393/02/15

Ethics committee reference number

5/4/1251

Health conditions studied

1

Description of health condition studied

Haematuria

ICD-10 code

R31

ICD-10 code description

Unspecified haematuria

Primary outcomes

1

Description

Haematuria

Timepoint

0,1,3, and 24 hours

Method of measurement

Urinary test tape

Secondary outcomes

1

Description

Haemoglobin

Timepoint

0, 6, and 24 hours

Method of measurement

CBC Analysis

Intervention groups

1

Description

For intervention group, We will administer 500 mg tranexamic acid (500mg/5cc, Tranexip, Caspianamin Drug Group, Iran) in 500cc N/S for bladder irrigation.

Category

Treatment - Drugs

2

Description

For control group, we will use 500 cc N/S with 10 cc pure water as placebo for bladder irrigation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research and Training Hospital

Full name of responsible person

Arezo Farjamnia

Street address

Golgasht avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohamadreza Rashidi

Street address

Golgasht Avenue

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Seyed Hossein Ojaghi Haghighi

Position

Medical Doctor/ Assistant Professor of Emergency
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty