

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effects of tranexamic acid on bleeding control during and after percutaneous nephrolithotomy (PCNL)

Protocol summary

Study aim

Effect of examines the effects of TXA on bleeding during and after PCNL.

Design

The intervention and control group each included 54 individuals who were randomly allocated. The intervention group received TXA (1gr at the beginning and 5mg every 8hrs for 3days) and the control group received placebo capsules (starch) of the same form and dose. The surgeon and patients were blind to the allocation of participants.

Settings and conduct

Totally, 108 patients in Imam Khomeini Hospital in Urmia- Iran took part in this double blind clinical trial study in 2013-2014.

Participants/Inclusion and exclusion criteria

Inclusion criteria were having kidney or ureteral stone (stones bigger than 2cm at pelvic or upper calices and bigger than 1.5cm of lower calices), failed ESWL, and candidate of PCNL. In addition, patients with a history of DVT, PTE, and Cr>1.5, drug allergy, cerebral arteries damage or SAH, color blindness, using OCP pills, using coagulation factors, surgery and heartvalve transplantation were excluded.

Intervention groups

tranexamic acid

Main outcome variables

Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180625040232N4**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **retrospective**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Saman Farshid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

farshid.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

2013-08-23, 1392/06/01

Actual recruitment end date

2014-05-20, 1393/02/30

Trial completion date

2014-05-20, 1393/02/30

Scientific title

The effects of tranexamic acid on bleeding control during and after percutaneous nephrolithotomy (PCNL)

Public title

The effects of tranexamic acid on bleeding control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 years ASA class >III Not having

coagulopathy

Exclusion criteria:
Need to embed Double J Stent Prediction of need to transfusion during surgery Patients with coagulopathy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **108**
Actual sample size reached: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, all eligible patients were assigned to control and intervention (tranexamic) groups using random sequence extraction from the computer (via www.randomization.com) and simple randomization. The resulting random numbers, i.e. the allocation of patients to groups, was concealed using sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Random allocation was made among patients and assigned to Card Intervention Group No. 1 and to Plasbo Card Group No. 2. Participants and clinical caregivers were unaware of the allocation of individuals in each of the study groups involved and the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Resalat Blvd-Emergency Alley, Urmia, Vest Azarbaijan

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date

2013-12-03, 1392/09/12

Ethics committee reference number
IR.UMSU.REC.1392.162

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

D68.32

ICD-10 code description

Hemorrhagic disorder due to extrinsic circulating anticoagulants

Primary outcomes

1

Description

Bleeding

Timepoint

24 hours before surgery and 48 hours after surgery

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Hospital stay days

Timepoint

Once, at the time of discharge

Method of measurement

Calculating hospital stay days from admission to discharge

Intervention groups

1

Description

Intervention group: In the intervention group, 1 gr of tranexamic acid (Caspian Tamin Pharmaceutical Company) is diluted in 100 ml normal saline and injected into nephrostomy drain (intravenously) immediately after surgery. The catheter is then clamped for 30 minutes to prevent leakage.

Category

Treatment - Drugs

2

Description

Control group: In the control group received placebo (1gr at the beginning and 5mg every 8hrs for 3days) capsules (starch) of the same form and dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital of Urmia

Full name of responsible person

Saman Farshid

Street address

Imam Khomeini hospital, Ershad Ave, Urmia

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Farshid.s@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saman Farshid

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

No

Title of funding source

Urmia 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

Oroumia University of Medical Sciences

Full name of responsible person

Saman Farshid

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Saman Farshid

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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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

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

Any information without the need for patients' names will be available

When the data will become available and for how long

Six months after publication

To whom data/document is available

Faculty members of medical universities

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

Email to Dr. Saman Farshid farshid.s@umsu.ac.ir

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

Email to Dr. Saman Farshid farshid.s@umsu.ac.ir

Comments