Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment of topical tranexamic effect on postoperative hemoglobin in patient undergoing percutaneous nephrolithotomy

Protocol summary

Study aim
Assessment of topical tranexamic effect on postoperative hemoglobin in patient undergoing percutaneous nephrolithotomy

Design
A randomized controlled clinical trial, double-blind, with parallel groups, on 90 patients

Settings and conduct
In this double-blind clinical trial study, 90 patients undergoing percutaneous nephrolithotomy were randomly divided into two groups, topical tanzanexamic acid and control (without tranexamic acid injection). In the intervention group, 1 gr of tranexamic acid was diluted in 100 ml of normal saline and injected into the nephrostomy drain immediately after surgery. The variables studied in this study included comparison of two groups for hemoglobin before and 48 hours after surgery, and number of days hospitalized. In this study, clinical care giver and statistical analyzer were not aware of groups assigned to patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria were age between 18-65 years, ASA class <III and absence of coagulopathy. Exclusion criteria included the need for Double J insertion, prediction of need for blood transfusions during surgery, and dyscrasia.

Intervention groups
Intervention group: Topical injection of tranexamic acid in nephrostomy drain - Control group: Non-injection of tranexamic acid

Main outcome variables
Hemoglobin, hospital stay days, stone free rate (SFR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180625040232N2**

Registration date: **2020-03-25, 1399/01/06**

Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**

Update count: **0**

Registration date

2020-03-25, 1399/01/06

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

2020-01-01, 1398/10/11

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

2020-01-01, 1398/10/11

Actual recruitment end date

2020-03-04, 1398/12/14

Trial completion date

2020-03-04, 1398/12/14

Scientific title

Assessment of topical tranexamic effect on postoperative hemoglobin in patient undergoing percutaneous nephrolithotomy

Public title

Effect of topical tranexamic on hemoglobin

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 Prediction of need to transfusion during surgery Having dyscrasia
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**
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
In this study, clinical care giver and statistical analyzer were not aware of groups assigned to patients.
Placebo
Not 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
Urmia University of Medical Sciences-Resalat Blvd-Emergency Alley, Urmia, Vest Azarbaijan
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-12-30, 1398/10/09
Ethics committee reference number
IR.UMSU.REC.1398.422

Health conditions studied

1

Description of health condition studied
Hemorrhagia
ICD-10 code
D68.32
ICD-10 code description
Hemorrhagic disorder due to extrinsic circulating anticoagulants

Primary outcomes

1

Description
Hemoglobin
Timepoint
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

2

Description
Stone free rate (SFR)
Timepoint
Once, when leaving the operating room
Method of measurement
Using Portable Radiological Device (C-arm)

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 (not intravenously) immediately after surgery. The catheter is then clamped for 30

minutes to prevent leakage.

Category

Treatment - Drugs

2

Description

Control group: In this group, routine procedures were performed after percutaneous nephrolithotomy. Therefore, tranexamic acid is not routinely administered, so it was not injected in this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital of Urmia

Full name of responsible person

Vahid Rezvankhah

Street address

Imam Khomeini hospital, Ershad Ave, Urmia

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5714783734

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samanf63@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Urmia University of Medical Sciences-Resalat Blvd-Emergency Alley. Urmia Vest Azarbaijan

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Email

mohebbi_iraj@yahoo.co.uk

Web page address

http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=fa

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

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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