

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 tranexamic 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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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

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Fax

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Email

mohebbi_iraj@yahoo.co.uk

Web page address

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

a

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

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Full name of responsible person

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Position

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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