Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the Efficacy of Tranexamic Acid in Reducing Blood Loss in Percutaneous Nephrolithotomy (PCNL)

Protocol summary

Study aim
Evaluation of the efficacy of tranexamic acid in reducing blood loss in per-cutaneous nephrolithotomy (PCNL)

Design
Two arm parallel group randomized double-blinded clinical trial

Settings and conduct
After obtaining required permissions from the research ethics committee, this randomized double-blinded clinical trial was done on 140 patients who undergoing percutaneous nephrolithotomy between September 2016 to November 2017 at Al-Zahra Hospital, a tertiary medical institute affiliated to Medical University of Isfahan based in Isfahan, Iran. Study population was randomized into two groups: those who received tranexamic acid (case group) and those who received placebo (control group). Patients in case group, received 1 gr of tranexamic acid intravenously at the initiation of the procedure, continued by IV infusion of 1 gr tranexamic acid at 8 hourly intervals for the first 48 hours after surgery to reach maximum total dose of 6 gr. For allocation of the participants, a computer-generated list of random numbers was used. Allocation concealment was assured using opaque, sealed envelopes. Patient demographics and clinical features were recorded. Percutaneous nephrolithotomy was done. Postoperative hemoglobin drop, number of packed-cells transfused, length of stay, and adverse effects were documented.

Participants/Inclusion and exclusion criteria
Patients older than 18 years of age with renal stone

Intervention groups
Tranxamic acid group (case group) and placebo group (control group)

Main outcome variables
Hemoglobin drop; number of transfusions; postoperative length of stay; drug adverse effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150420021869N1**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **retrospective**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date
2018-03-04, 1396/12/13

Registrant information

Name
Farshad Gholipour

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 6636 2089

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-09-10, 1395/06/20

Expected recruitment end date
2017-09-11, 1396/06/20

Actual recruitment start date
2016-09-10, 1395/06/20

Actual recruitment end date
2017-11-01, 1396/08/10

Trial completion date
empty

Scientific title
Evaluation of the Efficacy of Tranexamic Acid in Reducing Blood Loss in Percutaneous Nephrolithotomy (PCNL)

Public title
Tranexamic acid in percutaneous nephrolithotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients older than 18 years of age with renal stone Serum creatinin level of 1.5 mg/dL or less

Exclusion criteria:
history of allergy to tranexamic acid Ongoing arterial or venous thrombosis Creatinine level of more than 1.5 mg/dL Acquired defective color vision Subarachnoid hemorrhage Concurrent use of oral contraceptives

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **120**
Actual sample size reached: **122**

Randomization (investigator's opinion)
Randomized

Randomization description
Study population was randomized into two groups: those who received tranexamic acid (case group) and those who received placebo (control group). Patients in case group, received 1 gr of tranexamic acid intravenously at the initiation of the procedure, continued by IV infusion of 1 gr tranexamic acid at 8 hourly intervals for the first 48 hours after surgery to reach maximum total dose of 6 gr. For allocation of the participants, a computer-generated list of random numbers was used. Allocation concealment was assured using opaque, sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Allocation concealment was assured using opaque, sealed envelopes. Anesthesia technician received the envelope and administered either tranexamic acid or normal saline prior to the procedure. The patient was given general anesthesia and was unaware of the received treatment and remained blinded after surgery. Two envelopes with the same information about treatment allocation were created. The second envelope was given to the nurse for postoperative drug administration.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Hezarjerib Boulvard

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Approval date
2017-02-02, 1395/11/14

Ethics committee reference number
396043

Health conditions studied

1

Description of health condition studied
Renal stone, bleeding, percutaneous nephrolithotomy

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Hemoglobin drop

Timepoint
Prior to surgery, 4 hours after surgery, post-op days one and two

Method of measurement
Blood sample examination

2

Description
Number of transfusions

Timepoint
Postoperative days

Method of measurement
Checklist

3

Description

Postoperative length of stay

Timepoint

Postoperative days

Method of measurement

Checklist

4

Description

Drug adverse effect

Timepoint

Postoperative days

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: tranexamic acid (TRANEXIP, Caspian Tamin Pharmaceutical Company, Iran) which is an antifibrinolytic drug and inhibits plasminogen activation;10 mL of 100 mg/mL injectable solution per dose administered intravenously and repeated at 8 hourly intervals to reach maximum dose of 6 gr.

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Farshad Gholipour

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Hezarjarib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahhedian Attar

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Farshad Gholipour

Position

Resident of Urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is no more information.

When the data will become available and for how long

There is no more information.

To whom data/document is available

There is no more information.

Under which criteria data/document could be used

There is no more information.

From where data/document is obtainable

There is no more information.

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

There is no more information.

Comments

There is no more information.