Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Farshad Gholipour

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Farshad Gholipour
Position
Resident of 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.