

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of Tranexamic acid on bleeding and hemoglobin level in patients with staghorn calculus

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of Tranexamic acid on bleeding and hemoglobin level in patients with staghorn calculi underwent percutaneous nephrolithotomy

##### Design

Studies groups: patients with staghorn calculus(kidney stone) Study:Randomized , blinded, sham controlled clinical trial with a parallel group The size of sample was 120 clinical trial phase: phase 3

##### Settings and conduct

Place of study: Alzahra Hospital, Isfahan Patients according to stone size were divided to two group (n=60). Then these patients were randomly divided into two groups(case and control) The study is a double blind clinical trial. The patient and the caregiver did not know how to allocate placebo and drug for patients

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with staghorn calculi candidate for percutaneous nephrolithotomy surgery.  
exclusion criteria: renal failure, consumption of vitamin E, Aspirin and warfarin and creatinine more than 15

##### Intervention groups

Intervention group: transaxamic acid (as drug) Control group: normal salin (as placebo)

##### Main outcome variables

Bleeding; Hemoglobin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180209038673N1**

Registration date: **2018-04-17, 1397/01/28**

Registration timing: **retrospective**

Last update: **2018-04-17, 1397/01/28**

Update count: **0**

##### Registration date

2018-04-17, 1397/01/28

##### Registrant information

###### Name

Robab Sheikhpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3623 5958

###### Email address

r.sheikhpour@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-01-31, 1395/11/12

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

2017-01-31, 1395/11/12

##### Actual recruitment end date

2017-10-23, 1396/08/01

##### Trial completion date

empty

##### Scientific title

The effect of Tranexamic acid on bleeding and hemoglobin level in patients with staghorn calculus

##### Public title

Effect of Tranexamic acid in treatment of surgical bleeding

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

patients with staghorn calculus candidate for

percutaneous nephrolithotomy surgery

**Exclusion criteria:**

renal failure creatinine more than 15 consumption of vitamin E, Aspirin and warfarin

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **120**

Actual sample size reached: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We divide each referral into two groups using a randomized table. This table is a collection of numbers. Consider numbers from 1 to 30 for intervention A and numbers 31 to 60 for control B(for both group size more and less than 4 cm). Then let's move on one of the numbers and move in one of the preset directions and assign the numbers to one of the groups. Thus, patients are completely randomly divided

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, patients did not aware about prescription drugs (placebo and medication). Also, the person who provided these drugs to patients had no information about the allocation of patients to drug or placebo

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study, 120 patients with kidney stones are divided into two groups based on stone size (larger and smaller than 4 cm). Then, patients in both groups were randomly divided into two groups (drug and placebo)

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Science, Hezar Jarib street, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2017-01-31, 1395/11/12

**Ethics committee reference number**

295188

**Health conditions studied**

1

**Description of health condition studied**

staghorn calculus kidney

**ICD-10 code**

N20

**ICD-10 code description**

Calculus of kidney and ureter

**Primary outcomes**

1

**Description**

Bleeding

**Timepoint**

One week after the end intervention

**Method of measurement**

The amount of blood intake

**Secondary outcomes**

1

**Description**

Hemoglobin

**Timepoint**

One week after the end intervention

**Method of measurement**

CBC analysis

**Intervention groups**

1

**Description**

Intervention group: Administration of 1 grTranexamic acid every 12 hours for a week(group with size more and less than 4 cm)

**Category**

Treatment - Drugs

2

**Description**

Control group: Normal Salin (group with size more and less than 4 cm)

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Mehrdad Mohammadi

**Street address**

Alzahra hospital, Soffeh Blvd, Keshvari Street

**City**

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8174675731

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mehrdad.mohammadi981@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Reseach deputy of Isfahan University of Medical Science

**Full name of responsible person**

Ahmad Movahedian 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**

Reseach deputy of Isfahan University of Medical Science

**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**

Abbas Barzegar

**Position**

Resident

**Latest degree**

Medical doctor

**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)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no reason for this decision

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available