

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

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

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

Street address

Isfahan University of Medical Science,Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 2020

Email

mehrdad.mohammadi981@gmail.com

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

Street address

Isfahan University of Medical Science,Hezar Jarib street, Isfahan

City

اصفهان

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 2020

Email

mehrdad.mohammadi981@gmail.com

Person responsible for scientific 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

Street address

Isfahan University of Medical Science,Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3620 2020

Email

mehrdad.mohammadi981@gmail.com

Person responsible for updating data

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

Street address

Isfahan University of Medical Science, Hezar Jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

817467573

Phone

+98 31 3620 2020

Email

mehrdad.mohammadi981@gmail.com

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