

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Study of the Hemostatic Effect of Transamin on percutaneous nephrolithotomy surgery

Protocol summary

Study aim

Determination of hemostatic effect of transamine in percutaneous nephrolithotomy.

Design

Clinical trials have two groups: patient and control, which is a blind side. At the beginning of the study, patients receive their own number regardless of the information in the file, which will be randomly assigned to the patient and control group.

Settings and conduct

This study was performed in patients who referred to Baqiyatallah Hospital who underwent surgery to remove a kidney stone. Patients in the patient group will receive the ampoule of transaminase according to a specific schedule, and participants in the control group will receive distilled water by inducing the same drug.

Participants/Inclusion and exclusion criteria

Participants in this study must be between 18 and 60 years old and weigh between 60 and 99 kg, and have no history of anticoagulant use or blood diseases. Therefore, patients under 18 years of age or over 60 years of age and weighing less than 60 kg and over 99 kg, as well as people with a history of anticoagulant use and a history of blood diseases will be excluded from the study.

Intervention groups

In this study, in order to investigate the coagulation effect of transaminase, a 500 mg trans amine ampoule will be used during surgery and also every 8 hours after surgery for 48 hours in the patient group And for the control group, distilled water vial will be used with the same program.

Main outcome variables

Decreased hemoglobin, blood transfusion, change in vital signs, heart attack, stroke, pulmonary thromboembolism, deep vein thrombosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200526047576N1**

Registration date: **2021-04-01, 1400/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-01, 1400/01/12**

Update count: **0**

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

seyyedmojtaba mirzadehgoodarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7710 2386

Email address

seyyedmojtabamirzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of the Hemostatic Effect of Transamin on percutaneous nephrolithotomy surgery

Public title

effect of transamin in percutaneous nephrolithotomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients should be between 18 and 60 years old Patients weigh between 60 kg and 99 kg

Exclusion criteria:

History of anticoagulant use History of blood diseases or HB less than 11 or PLT less than 140000

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the study, a simple randomization method with individual units is used in such a way that patients are randomly assigned to one of the two intervention and control groups by choosing one of the cards containing code A or B. Cards A and B are each prepared in 32 pieces and placed in 64 exactly the same envelopes randomly and will be sealed. The cards will be placed in envelopes by someone outside the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

in order to avoid targeting and guiding the results, information related to the purpose of the project will be refused to the data analyzer. Efforts will be made to ensure that participants are anonymous and kept secret from the analyst. Participants will be analyzed in two unnamed groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethic committee of baqiyatallah university of medical sciences

Street address

baqiyatallah hospital, sheikh bahaie street, mollasadra Blvd, vanak square.

City

tehran

Province

Tehran

Postal code

1435915371

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1399.046

Health conditions studied**1****Description of health condition studied**

kidneys stag horn stone

ICD-10 code

N20.0

ICD-10 code description

calculus of kidney

Primary outcomes**1****Description**

Decreased hemoglobin loss

Timepoint

The day before surgery and then daily for 3 days

Method of measurement

Patient tests- series of CBC

Secondary outcomes**1****Description**

Hb

Timepoint

Patients' hemoglobin levels will be measured a day before surgery and then daily for three days after surgery.

Method of measurement

Complete blood count

2**Description**

blood pressure

Timepoint

every 6 hr

Method of measurement

evaluation of blood pressure

3**Description**

heart rate

Timepoint

every 6 hours

Method of measurement

evaluation of heart rate

4**Description**

respiratory rate

Timepoint

every 6 hours

Method of measurement

evaluation of respiratory rate

Intervention groups**1****Description**

According to the purpose of the project in the intervention group, 500 mg transamine ampoule containing 500 mg tranexamic acid in 5 ml by injection; During surgery, it will be used by an anesthesiologist and then every 8 hours to 48 hours by a respected research nurse. All patients are examined for vital signs every 6 hours by a respected ward nurse and a detailed description of the changes will be provided. Before starting the project, a training session will be held for all project partners and patients. All medicines will be provided by Caspian Tamin Company. No medication or placebo will be used for the control group.

Category

Treatment - Surgery

2**Description**

Control group: in the control group, there will be no intervention in the patient's treatment process, and only to check and compare the control group with the intervention group, the vital signs of patients admitted to this group will be measured every 6 hours by a respected nurse partner. For these patients, a full explanation will be provided before the procedure begins.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mollasadra street. Vanak.Tehran. Baquatallah Hospital.

Full name of responsible person

Seyyedmojtaba Mirzadeh Goodarzi

Street address

Mollasadra Street. Vanak.

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Email

Seyyedmojtabamirzadeh@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhossein Alishiri

Street address

Mollasadra street. Vanak

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Phone

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Email

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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

Bagheiat-allah 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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Fatemeh Heidari

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Phone

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Email

Seyyedmojtatabamirzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyyedmojtaba Mirzadeh Goodarzi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyyedmojtaba Mirzadeh Goodarzi

Position

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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

Given the need to use the information in this study to create treatment protocols, all cases must be published accurately.

When the data will become available and for how long

Simultaneously with the end of the study

To whom data/document is available

physicians and academic researchers

Under which criteria data/document could be used

The information in this study can be used to create a treatment protocol

From where data/document is obtainable

University dissertations

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

Due to the use of the information in this study in the university dissertation, the applicants can easily access all the information in this study.

Comments