

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effectiveness of limiting unwanted movements of Amplatz during percutaneous nephrolithotomy(PCNL) in reducing bleeding

Protocol summary

Study aim

Determining the mean decrease in hemoglobin induced by percutaneous nephrolithotomy(PCNL).

Design

The sample size required to estimate a relatively small effect, in a two-arm study with repeated repetition of hemoglobin 3 times (once before surgery and the second and third time between 6 and 24 hours after surgery) using G-POWER software, With an estimated 10% drop, 100 were estimated. Randomization with Balance-Blocked Randomization technique has been performed and prepared by an epidemiologist using 4 randomized balanced blocks.

Settings and conduct

Patients referred for percutaneous nephrolithotomy(PCNL) to the clinic of Hasheminejad Hospital in Tehran are placed in two random arms of 50. Nurses, patients and analyst do not know the identity of the intervention or control groups. According to the randomization table, the executor places the patients in two groups and provides the information to the analyst.

Participants/Inclusion and exclusion criteria

We include patients over 18 years old and kidney stones indicated for percutaneous nephrolithotomy(PCNL). Exclusion criteria include patients with a history of surgery or renal anomalies in the same kidney or coagulation disorders.

Intervention groups

In the control and intervention groups, PCNL is performed in the usual way. But in the intervention group, use of Amplatz clamp (a metal or plastic ring clamp that is placed around the Amplatz) limited the unwanted movements of the Amplatz by loosening or tightening the clamp screw. Also, by tying the skin suture thread (which is usually done at the end of the procedure) around the Amplatz clamp, preventing The Amplatz moves out of the patient's body. At the end of

the operation, this thread is opened around the Amplatz clamp and tied to the skin.

Main outcome variables

Decreased hemoglobin; Duration of operation; Number of access losses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201218049752N1**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Reza Elmimehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 3274

Email address

reza.elmimkehr@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of limiting unwanted movements of Amplatz during percutaneous nephrolithotomy(PCNL) in reducing bleeding

Public title

Effectiveness of limiting unwanted movements of Amplatz during PCNL

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 18 years who have kidney stones with indication for removal of kidney stones through the skin

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced-Blocked Randomization was done with quadruple blocks by epidemiologist by using Statistical software. Randomization table was provided to the project manager. According to the randomization table in the operating room, the project manager puts patients in two intervention or control groups and records the information confidentially. The facilitator provides patient information to the statistical analyzer without mentioning the identities of the individuals.

Blinding (investigator's opinion)

Double blinded

Blinding description

The facilitator gives a comprehensive explanation to all patients who enter the study about the type of interventions and their possible consequences, but by the end of the study, the patient does not know whether he is in the intervention group or not. During the hospitalization, the patient nurse does not know the identity of the patients in the intervention or control group. According to the randomization table in the operating room, the project manager places the patients in the intervention or control group and records the information. The total information recorded is provided to the analyzer in the form of numbers and without the

patient's identity.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical Sciences

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Hasheminejad hospital, Vali-nejad Str, Vanak Sq, Vali-e-asr Str

City

Tehran

Province

Tehran

Postal code

1969714713

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.IUMS.FMD.REC.1400.471

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

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

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

Hemoglobin changes

Timepoint

Measurement of patient hemoglobin in milligram per deciliter the day before surgery and 6 and 24 hours after surgery

Method of measurement

Laboratory

Secondary outcomes

1

Description

Amplatz position

Timepoint

during surgery

Method of measurement

questionnaire

2

Description

Duration of operation

Timepoint

The number of minutes elapsed from the beginning to the end of the operation

Method of measurement

Patient file

Intervention groups

1

Description

Control group: First, with the help of a retrograde fluoroscope and pyelography, insert a special needle and then a guidewire into the kidney, make an incision of about one centimeter on the skin and dilate the skin-to-kidney route to 30 French. In the next step, a plastic tube called Amplatz is guided on the dilator into the kidney. Then the dilator is removed and the Amplatz remains to the end of the operation. Then, stone crushing is performed with a nephroscope and lithoclast. Then the stone pieces are removed through the Amplatz. At the end of the operation, the tube is removed and the skin defect is sutured.

Category

Treatment - Surgery

2

Description

Intervention group: First, with the help of a retrograde fluoroscope and pyelography, insert a special needle and then a guidewire into the kidney. Make an incision of about one centimeter on the skin. We pass the needle and suture (In the control group, it was performed at the end of the operation) through the skin defect without tying. Then we dilate the skin to kidney route up to 30 French. In the next step, a plastic tube called Amplatz is guided on the dilator into the kidney. Then the dilator is removed and the Amplatz remains. Mount a screw ring clamp on the Amplatz and tie the thread through the skin defect around it so that the Amplatz is fixed to the skin. By tightening or loosening the screw, it is possible to stabilize or release the Amplatz. Stone crushing is performed with a nephroscope and lithoclast. Then the stone pieces are removed through the Amplatz. At the end of the operation, the suture knot is untied from the Amplatz, so it removed and the suture is tied at the site of the skin defect.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad hospital

Full name of responsible person

Reza Elmimehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Kiwani

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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

Iran 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

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Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Elmimkehr

Position

Fellowship Assistant

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available