Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effectiveness of limiting unwanted movementes 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 a 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)

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Email address

reza.elmimehr@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 movementes of Amplatz during percutaneous nephrolithotomy(PCNL) in reducing bleeding

Public title
Effectiveness of limiting unwanted movementes 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 down 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
Street address
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 miligram 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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Vali-nejad Str, Vanak Sq, Vali-e-asr Boul, Tehrah, Iran.
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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
Street address
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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

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Reza Elmimehr

Position
Fellowship Assistant

Latest degree
Specialist

Other areas of specialty/work
Urology

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Hosheminejad Hospital, Vali-nejad Str, Vank Sq, Vali-e-asr St

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Person responsible for updating data

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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