Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of blood loss and complications in patients underwent percutaneous nephrolithotomy with balloon traction of nephrostomy and conventional methods: a randomized clinical trial

Protocol summary

Study aim

A clinical trial to compare the amount of bleeding and surgical complications of percutaneous nephrolithotomy in a group that had a balloon nephrostomy compared to a normal nephrostomy

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 102 patients.

Settings and conduct

Labbafinejad Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: kidney stone candidate for PCNL surgery Age 18 years and older Placement in group one ASA 1,2 in terms of anesthesia risk Exclusion criteria: Age less than 18 years Patients with kidney stones with anatomical abnormalities (malrotation, pelvic kidney and horseshoe kidney) Patients with kidney parenchymal atrophy and kidney with little function Placement in ASA grade 3 group in terms of anesthesia risk Patients with high creatinine (<1.5 mg/dL) BMI greater than 30 Untreated coagulation disorder Aspirin consumption in the last seven days Taking NSAID drugs in the last 5 days Untreated active urinary tract infection

Intervention groups

In the first group, a balloon nephrostomy was placed under fluoroscopy control at the infundibulum entrance of the access site from the pelvic side, and with a brief traction on the balloon, tamponade will performed on the calyx of the access site. In the second group, which is the control group, the nephrostomy point is implanted in the conventional way. Then the hemoglobin decrease and complications in these two groups will compared.

Main outcome variables

Stone clearance, transfusion rate, hemoglobin changes, urinary leakage volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160406027253N2**
Registration date: **2023-10-02, 1402/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-02, 1402/07/10**
Update count: **0**

Registration date

2023-10-02, 1402/07/10

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 88644466

Email address

ahkashi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2023-12-01, 1402/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of blood loss and complications in patients underwent percutaneous nephrolithotomy with balloon traction of nephrostomy and conventional methods: a randomized clinical trial

Public title
A clinical trial to compare the amount of bleeding and surgical complications of percutaneous nephrolithotomy in a group that had a balloon nephrostomy compared to a normal nephrostomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Kidney stones are candidates for PCNL surgery Age 18 years and older Placement in group one ASA I,II in terms of anesthesia risk

Exclusion criteria:
Age under 18 years old Patients with kidney stones with anatomical abnormalities(Renal malrotation, pelvic kidney, horseshoe kidney Paranchymal atrophy and kidney with little function Placement in group one ASA III in terms of anesthesia risk High Creatinine BMI over 30 Kg/m2 Untreated coagulation disorder Aspirin consumption in the last 7 days Taking NSAID drugs in the last 5 days Untreated active urinary tract infection

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process has already been done by Stata software, and the number of patients has been divided into binary and quadruple blocks by using the Random allocation command in Stata, and the patient number and the group in which the random allocation is placed in the sealed envelopes. At the end of the operation, the envelopes are opened and based on the contents of the envelope, a normal nephrostomy or a balloon nephrostomy is placed inside the pelvis and the balloon is filled a little and then traction is applied on the skin to put pressure on the calyx of the access site.

Blinding (investigator's opinion)
Double blinded

Blinding description
Equality of nephrostomy ends outside body ensures the unawareness of participants to allocation groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Kidney Diseases Research Center- Shahid Beheshti University of Sciences

Street address
No. 44, Pasdaran St., Shahid Jafari St. (9th Bostan), next to Shahid Labaghinejad Hospital, Tehran

City
Tehran

Province
Tehran

Postal code
1666663111

Approval date
2022-12-25, 1401/10/04

Ethics committee reference number
IR.SBMU.UNRC.REC.1401.030

Health conditions studied

1

Description of health condition studied
kidney stone

ICD-10 code
N 20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Stone cleaning

Timepoint
24 hours after the intervention

Method of measurement
Plain radiography of the abdomen

2

Description
Transfusion Rate

Timepoint
From the start of surgery until time of discharge from the hospital

Method of measurement
The number of units of blood transfused during hospitalization

3

Description
Urinary leak volume
Timepoint
During hospitalization
Method of measurement
CC volume of urine removed from the nephrostomy site

4

Description
Changes in hemoglobin
Timepoint
End of operation and 24 hours after surgery
Method of measurement
mg/dL based on laboratory measurement

Secondary outcomes

1

Description
creatinine change
Timepoint
preoperative and 24-48 hours after surgery
Method of measurement
based on serum levels of creatinine before and after operation

2

Description
hospitalization duration
Timepoint
from hospitalization to discharge
Method of measurement
days

Intervention groups

1

Description
Intervention group: In the intervention group, a balloon nephrostomy was placed under fluoroscopy at the infundibulum entrance of the access site from the pelvic side, and tamponade was performed on the calyx of the access site with brief traction on the balloon.
Category
Treatment - Surgery

2

Description
Control group: In the control group, which is the control group, the nephrostomy point was inserted in the conventional way. Then the hemoglobin drop and complications in these two groups were compared.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Labafinejad Hospital
Full name of responsible person
Dr. Amirhossein Kashi
Street address
No. 44, Pasdaran St., Shahid Jafari St. (9th Bostan), next to Shahid Labaghinejad Hospital, Tehran
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Postal code
1666663111
Phone
+98 21 2256 7222
Email
ahkashi@gmail.com
Web page address
https://lamc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Basiri
Street address
Pasdaran st., 9th Boustan st.,
City
Tehran
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Postal code
1666663111
Phone
+98 21 2277 0954
Email
info@unrc.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Amirhossein Kashi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

No. 44, Pasdaran St., Shahid Jafari St. (9th Bostan), next to Shahid Labaghinejad Hospital, Tehran

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ahkashi@gmail.com

Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Nouralizadeh

Position

Asssociate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Amirhossein Kashi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

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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

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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Non-secret data of the study will be published in the official website of the Urology and Nephrology Research Center and will be accessible for all people for 5 years.

When the data will become available and for how long

Non-secret data of the study will be published in the official website of the Urology and Nephrology Research Center and will be accessible for all people for 5 years.

To whom data/document is available

Non-secret data of the study will be published in the official website of the Urology and Nephrology Research Center and will be accessible for all researchers for 5 years.

Under which criteria data/document could be used

Will be dependent of the policy of the journal in which the article will be published.

From where data/document is obtainable

unrc website stated above

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

request on website --> confirmation by UNRC manager --> access given

Comments