

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of routine use of Foley catheter balloon as nephrostomy in percutaneous nephrolithotomy patients

Protocol summary

Study aim

To evaluate the effectiveness and safety of Foley balloon catheters compared with non-balloon catheters as nephrostomy tubes after percutaneous nephrolithotomy (PCNL).

Design

Clinical trial with a control group, parallel design, double-blind, randomized, conducted on 200 patients. Randomization was performed using block randomization.

Settings and conduct

Patients eligible for percutaneous nephrolithotomy (PCNL) who visit Shahid Modarres Hospital, in Tehran, Iran, from November 2025 to March 2026, will be enrolled if they meet the inclusion criteria. They will be randomly assigned to the intervention group (Foley catheter with balloon) or the control group (non-balloon nephrostomy tube) using blocks of 4. The study will be conducted as double-blind, with patients, surgeons, and data analysts unaware of the intervention type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 70 years; presence of renal stones in the upper urinary tract with a diameter greater than 2 cm; eligibility for percutaneous nephrolithotomy (PCNL); and provision of written informed consent. Exclusion criteria: Patients with severe bleeding requiring a conventional balloon; patients with a solitary kidney; patients receiving anticoagulant therapy; pregnant patients; and those with active infection or sepsis.

Intervention groups

Intervention group: Patients undergoing percutaneous nephrolithotomy (PCNL) with a Foley catheter with balloon (16 French, 5 mL balloon) placed in the upper urinary tract, maintained for 48 hours post-procedure, manufactured by Bard Medical. Control group: Patients undergoing percutaneous nephrolithotomy (PCNL) with a non-balloon nephrostomy tube (16 French) placed at the surgical site, maintained for 48 hours post-

procedure, manufactured by Bard Medical.

Main outcome variables

Blood hemoglobin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250413065309N1**

Registration date: **2025-11-09, 1404/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2025-11-09, 1404/08/18**

Update count: **0**

Registration date

2025-11-09, 1404/08/18

Registrant information

Name

Mostafa Farajpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7729 1971

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-22, 1404/07/30

Expected recruitment end date

2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of routine use of Foley catheter balloon as nephrostomy in percutaneous nephrolithotomy patients

Public title
Evaluating the Effect of Balloon Catheters in Reducing Complications of Percutaneous Nephrolithotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Presence of a stone in the upper urinary tract Stone with a diameter greater than 2 cm Written informed consent to undergo surgery
Exclusion criteria:
Patients with significant bleeding requiring classical balloon placement. Single-kidney patients Patients on anticoagulant therapy Pregnant patients infection or sepsis

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized into two groups (nephrostomy with balloon vs. without balloon) using a computer-generated random sequence created by Randomizer.org and the block randomization method (block size = 4) to ensure balance between groups. Allocation concealment was achieved using opaque, sealed, and sequentially numbered envelopes prepared by an independent researcher to minimize allocation bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double-blinding was implemented. The primary surgeon was blinded to group allocation, with nephrostomy placement performed by surgical assistants to maintain blinding.

Placebo
Not used

Assignment
Parallel

Other design features
The study used Guy's Stone Score to standardize stone complexity across groups, ensuring comparability.

Nephrostomy tube placement was confirmed using fluoroscopic guidance with contrast injection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the Vice Chancellor for Research and Technology, SBMU

Street address

Building No. 2, University Headquarters, Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2025-08-17, 1404/05/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.384

Health conditions studied

1

Description of health condition studied

Kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Blood hemoglobin level

Timepoint

Measurement of blood hemoglobin level on the day before surgery (baseline), and on days 2 and 7 after surgery.

Method of measurement

Hematology analyzer

Secondary outcomes

1

Description

Transfusion rate

Timepoint

2 days and 7 days after the intervention.

Method of measurement

Review of patients' medical records and data collection by the researcher using a standardized checklist, verified by the hospital blood bank records.

Intervention groups

1

Description

Intervention group: Placement of a Foley catheter with balloon (16 French, 5 mL balloon) in the upper urinary tract following percutaneous nephrolithotomy (PCNL), maintained for 48 hours post-surgery, manufactured by Bard Medical.

Category

Treatment - Devices

2

Description

Control group: Placement of a non-balloon nephrostomy tube (16 French) at the surgical site following percutaneous nephrolithotomy (PCNL), maintained for 48 hours post-surgery, manufactured by Bard Medical.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid modarres hospital

Full name of responsible person

mostafa farajpour

Street address

Shahid Modarres Hospital, Saadatabad St., Darya Blvd., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences,

Shahid Shahriari Square, Daneshjou Boulevard,
Shahid Chamran Highway, Tehran, Iran

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research@sbmu.ac.ir

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

Mostafa Farajpour Khanaposhtani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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

Due to ethical and institutional constraints, including patient privacy concerns and the absence of a secure data-sharing platform compliant with national regulations, deidentified individual participant data will not be shared at this time.

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