Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 200patients. 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)

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+98 21 7729 1971

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mostafa.farajpour.kh@gmail.com

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

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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
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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
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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
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
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Position
Assistant professor
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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