# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

**Phone**
+98 21 7729 1971

**Email address**
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**

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
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۹۹۸۷۳۴۳۸۳
**Phone**
+98 21 2207 4090
**Email**
Mostafa.farajpour.kh@gmail.com

## 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
**City**
Tehran
**Province**
Tehran
**Postal code**
1983969411
**Phone**
+98 21 2243 9864
**Email**
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
**Street address**
Shahid Modarres Hospital, Saadatabad St., Darya Blvd., Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4090
**Email**
Mostafa.farajpour.kh@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Mostafa Farajpour
**Position**
assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Urology
**Street address**
Shahid Modarres Hospital, Saadatabad St., Darya Blvd., Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4090
**Email**
Mostafa.farajpour.kh@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Mostafa Farajpour
**Position**
assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Urology
**Street address**
Shahid Modarres Hospital, Yadegar-e-Imam Highway, Saadat Abad Intersection, Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1998734383
**Phone**
+98 21 2207 4090
**Email**
Mostafa.farajpour.kh@gmail.com

## 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