

# 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 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

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

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##### 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

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##### Province

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##### 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

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Tehran

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## 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

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**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**

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**Email**

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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