Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Balloon Traction Nephrostomy versus Conventional Nephrostomy Placement in Reducing Hemoglobin Drop in Patients with a Solitary Pelvic Stone Undergoing Percutaneous Nephrolithotomy

Protocol summary

Study aim

Determining and Comparing thw Effectiveness of Balloon Traction Nephrostomy versus Conventional Nephrostomy Placement in Reducing Hemoglobin Drop in Patients with a Solitary Pelvic Stone Undergoing Percutaneous Nephrolithotomy

Design

A randomized, non-blinded/open label clinical trial, with the parallel groups, Phase 3 on 130 patients

Settings and conduct

In this randomized non-blinded clinical trial, 130 eligible patients presenting to Al-Zahra and Khorshid Hospitals in Isfahan will be included in the study and randomly divided into two groups. The first group will undergo percutaneous nephrolithotomy(PCNL) using the balloon method, and the second group will undergo PCNL using the conventional method. Subsequently, the degree of bleeding reduction in patients will be assessed and compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with a solitary pelvic stone undergoing percutaneous nephrostomy, aged 18 years and older. Exclusion criteria include patients with a history of anticoagulant use or uncorrected coagulopathy disorders, a history of renal failure, a history of untreated urinary tract infection, a history of severe pre-existing anemia, a history of flank surgery, patients with a solitary kidney, a history of renal anomalies, a history of vascular diseases, and patients who required angioembolization during a previous percutaneous nephrolithotomy (PCNL).

Intervention groups

Intervention group: At the end of the percutaneous nephrolithotomy (PCNL) procedure, patients will receive a balloon nephrostomy tube placed into the urinary collecting system. Control group: At the end of the PCNL procedure, patients will receive a conventional non-balloon nephrostomy tube, or if a balloon catheter is used, the balloon will not be inflated.

Main outcome variables

Hemoglobin, Hematocrit, Hydronephrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N88**
Registration date: **2026-05-03, 1405/02/13**
Registration timing: **prospective**

Last update: **2026-05-03, 1405/02/13**
Update count: **0**

Registration date

2026-05-03, 1405/02/13

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-21, 1405/03/31

Expected recruitment end date
2027-01-20, 1405/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Balloon Traction Nephrostomy versus Conventional Nephrostomy Placement in Reducing Hemoglobin Drop in Patients with a Solitary Pelvic Stone Undergoing Percutaneous Nephrolithotomy

Public title
Comparison of Two Kidney Drainage Tube Placement Methods after Percutaneous Nephrolithotomy: Balloon (with Traction) versus Conventional Method, in Terms of Anemia Severity in Patients with a Solitary Pelvic Stone
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a Solitary Pelvic Stone Undergoing Percutaneous Nephrolithotomy Age group 18 years and older
Exclusion criteria:
History of anticoagulant use or having uncorrected coagulopathy disorders History of renal failure History of untreated urinary tract infection History of severe pre-existing anemia History of flank surgery (e.g., nephrolithotomy, pyeloplasty, ureterolithotomy, pyelolithotomy, etc.) Patients with a solitary kidney (due to compensatory hypertrophy or possible chronic kidney disease (CKD), the risk of bleeding is higher and acts as a confounder) History of renal anomalies such as horseshoe kidney and nephroptosis History of vascular diseases Patients who required angioembolization during a previous PCNL
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 130 eligible patients are randomly selected. For this, the letter A is written on 65 sheets, and the letter B is written on 65 sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Medicine - Isfahan University of Medical Sciences (Research Ethics Committee)
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2026-02-07, 1404/11/18
Ethics committee reference number
IR.MUI.MED.REC.1404.450

Health conditions studied

1

Description of health condition studied
Patients with a Solitary Pelvic Stone Undergoing Percutaneous Nephrolithotomy
ICD-10 code
N20.0
ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Hemoglobin
Timepoint
Before and after intervention
Method of measurement
Blood test

2

Description
Hematocrit
Timepoint
Before and after intervention

Method of measurement
Blood test

3

Description
Hydronephrosis
Timepoint
One week after the intervention
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At the end of the percutaneous nephrolithotomy (PCNL) procedure, patients will receive a balloon nephrostomy tube placed into the urinary collecting system. This tube will be an 18 Fr Foley catheter with a balloon, which will be inflated with a small volume depending on the renal anatomy. Gentle traction will be applied to the tube, and it will be secured to the skin with a suture. The tube will be kept in place for 24 hours.
Category
Treatment - Surgery

2

Description
Control group: At the end of the percutaneous nephrolithotomy (PCNL) procedure, patients will receive a conventional non-balloon nephrostomy tube, or if a balloon catheter is used, the balloon will not be inflated.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Reza Kazemi
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Department of Urology, Al-Zahra Hospital, Sofeh Blvd.
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2

Recruitment center
Name of recruitment center
Khorshid hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Kazemi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
There is no further information.
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