

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 the 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)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

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

Isfahan

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

Street address

Department of Urology, Al-Zahra Hospital, Sofeh Blvd.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Rezakazemi6788@gmail.com

2**Recruitment center****Name of recruitment center**

Khorshid hospital

Full name of responsible person

Reza Kazemi

Street address

Ostandari street.

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2127

Email

dr.rezakazemi6788@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Specialist

Other areas of specialty/work

Urology

Street address

Ostandari street.

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2127

Email

Rezakazemi6788@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Reza Kazemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Ostandari street.

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2127

Email

Rezakazemi6788@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahmood Valamehr

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Ostandari street.

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2127

Email

Valamehr71@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

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