Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the safety and efficacy of ultrasound-guided percutaneous nephrolithotomy versus conventional C-arm-guided percutaneous nephrolithotomy

Protocol summary

Study aim

Comparison of safety, efficacy, and practicality of ultrasound-guided percutaneous nephrolithotomy versus conventional C-arm-guided percutaneous nephrolithotomy

Design

Before surgery, the age, sex, and health status (ASA) of the patients will be recorded. Non-contrast ultrasound and CT scan and Guy's stone score will be performed for all patients. Stone weight will be calculated using the total stone size. Surgical technique All patients undergoing PCNL will be placed in the prone position. In FL-PCNL, a multidirectional movable C-arm fluoroscopy machine with an under-table X-ray generator will be used for imaging. Total screening time will be measured by the fluoroscopy machine. Estimated bleeding time and total operative time will also be recorded.

Settings and conduct

Golestan Hospital, Ahvaz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients aged 18–70 years with kidney stones 2–4 cm in diameter, ASA class I–III, normal coagulation tests (PT, aPTT, INR), informed consent Exclusion criteria included patients with coagulation disorders or anticoagulant use, pregnancy, history of hypersensitivity to epinephrine or hemostatic agents, acute urinary tract infection or sepsis

Intervention groups

This clinical trial will use a double-blind design to reduce potential bias in evaluating the effectiveness of the intervention. Participants will be randomly assigned (using a random number table) to two groups: ultrasound-guided percutaneous nephrolithotomy and conventional C-arm-guided percutaneous nephrolithotomy, with grouping information managed by a confidential coding system by the project administrator.

Main outcome variables

Ultrasound guidance is a reliable tool in the hands of experienced urologists to perform PCNL with low or even zero radiation, with fewer complications for patients and healthcare personnel.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250928067401N1**
Registration date: **2025-10-07, 1404/07/15**
Registration timing: **prospective**

Last update: **2025-10-07, 1404/07/15**
Update count: **0**

Registration date

2025-10-07, 1404/07/15

Registrant information

Name

Sirous Rafiei Asl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-30, 1404/08/08

Expected recruitment end date

2026-06-20, 1405/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the safety and efficacy of ultrasound-guided percutaneous nephrolithotomy versus conventional C-arm-guided percutaneous nephrolithotomy

Public title
Comparative study of the safety and efficacy of ultrasound-guided percutaneous nephrolithotomy versus conventional C-arm-guided percutaneous nephrolithotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria included patients aged 18–70 years with kidney stones 2–4 cm in diameter, ASA class I–III, normal coagulation tests (PT, aPTT, INR), informed consentExclusion criteria included patients with coagulation disorders or anticoagulant use, pregnancy, history of hypersensitivity to epinephrine or hemostatic agents, acute urinary tract infection or sepsis
Exclusion criteria:
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and the statisticians who analyze the data will not know the group assignment until the end of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
IR.AJUMS.REC.1404.283
Street address
Zip Code: 6135715794, Golestan Highway-Jundishapur University Ahvaz
City
ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2025-08-30, 1404/06/08
Ethics committee reference number
IR.AJUMS.REC.1404.283

Health conditions studied

1

Description of health condition studied
Nephrolithotomy
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Safety and efficacy of percutaneous nephrolithotomy
Timepoint
During and after surgery
Method of measurement
Based on laboratory results and during surgery

Secondary outcomes

empty

Intervention groups

1

Description
Ultrasound-guided percutaneous nephrolithotomy group
Category
Treatment - Surgery

2

Description
conventional C-arm-guided percutaneous nephrolithotomy group
Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Hospital, Ahvaz

Full name of responsible person
Sirous Rafiei Asl

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Zip Code: 6135715794,Ahvaz-Golestan Highway-Jundishapur University Ahvaz

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Sponsors / Funding sources

1

Sponsor

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Sirous Rafiei Asl

Position
Faculty member

Latest degree
Specialist

Other areas of specialty/work
Pathology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only part of the data, such as information related to the main outcome or the like, can be shared.
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
Research team
Under which criteria data/document could be used
According to the regulations of the Ministry of Health and Medical Education
From where data/document is obtainable
Responsible author and research team colleagues
What processes are involved for a request to access data/document
Two months
Comments