

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

+98 939 556 6827

Email address

rafieiasl-s@ajums.ac.ir

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 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.

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

Khuzestan

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

Street address

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

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 939 556 6827

Email

rafieiasl-s@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

sirous rafiei asl

Street address

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

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 0000

Email

rafieiasl-s@ajums.ac.ir

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

Street address

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

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 939 556 6827

Email

rafieiasl-s@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sirous Rafiei Asl

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Pathology

Street address

Ahvaz-Golestan Highway-Ahvaz Jundishapur
University

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 939 556 6827

Email

rafieiasl-s@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sirous Rafiei Asl

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pathology

Street address

Golestan Highway-Jundishapour University, Ahvaz

City

ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3311 0000

Email

rafieiasl-s@ajums.ac.ir

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