

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the treatment effect of percutaneous nephrolithotomy access to pyelocalyceal system through ultrasonography versus fluoroscopy in patients with kidney stone: a randomized clinical trial

Protocol summary

Summary

Objectives: Comparison of the treatment effect of percutaneous nephrolithotomy access to pyelocalyceal system through ultrasonography versus fluoroscopy. Design: A randomized clinical trial. Setting and conduct: The eligible patients with kidney stone who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; having kidney stone. Exclusion criteria: Cardiopulmonary disease; coagulopathy; untreated urinary tract infection; severe obesity with body mass index above 35. Intervention group 1: Percutaneous nephrolithotomy through ultrasonography. Intervention group 2: Percutaneous nephrolithotomy through fluoroscopy. Primary outcome: (a) amount of access to pyelocalyceal system through clinical evaluation during surgery; (b) duration of time to access to pyelocalyceal system through clinical evaluation during surgery. Secondary outcome: (a) hydronephrosis 24 and 48 hours after surgery through physical examination; (b) amount of bleeding during surgery through measuring volume of suctioned blood. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704089014N155**
Registration date: **2017-04-10, 1396/01/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-10, 1396/01/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the treatment effect of percutaneous nephrolithotomy access to pyelocalyceal system through ultrasonography versus fluoroscopy in patients with kidney stone: a randomized clinical trial

Public title

Comparison of the treatment effect of percutaneous nephrolithotomy access to pyelocalyceal system through ultrasonography versus fluoroscopy in patients with

kidney stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age of 18 to 65 years; having kidney stone. Exclusion criteria: Cardiopulmonary disease; coagulopathy; untreated urinary tract infection; severe obesity with body mass index above 35.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2017-01-14, 1395/10/25

Ethics committee reference number
IR.UMSHA.REC.1395.443

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
amount of access to pyelocalyceal system

Timepoint
during surgery

Method of measurement
through clinical evaluation

2

Description
duration of time to access to pyelocalyceal system

Timepoint
during surgery

Method of measurement
through clinical evaluation

Secondary outcomes

1

Description
hydronephrosis

Timepoint
24 and 48 hours after surgery

Method of measurement
through physical examination

2

Description
amount of bleeding

Timepoint
during surgery

Method of measurement
through measuring volume of suctioned blood

Intervention groups

1

Description
Intervention group 1: Percutaneous nephrolithotomy through ultrasonography.

Category
Treatment - Surgery

2

Description

Intervention group 2: Percutaneous nephrolithotomy through fluoroscopy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Poya Parsi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Poya Parsi

Position

Resident of Urology

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0283

Fax

Email

pouyaparsi6699@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Sasan Mehrabi

Position

Urologist

Other areas of specialty/work

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Postal code

Phone

+98 81 3838 0283

Fax

Email

mehrabi.sasan@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty