

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of normal saline irrigation temperature on surgical outcomes of patients undergoing percutaneous nephrolithotomy

Protocol summary

Registration timing: **prospective**

Study aim

Investigating the effect of normal saline irrigation temperature on surgical outcomes of patients undergoing percutaneous nephrolithotomy

Last update: **2023-10-27, 1402/08/05**

Update count: **0**

Registration date

2023-10-27, 1402/08/05

Design

A double-blind, randomized clinical trial study with parallel groups and phases 3 on 50 patients. Patients will be randomly divided into groups using generated-computer numbers by Random Allocation software.

Registrant information

Name

Saman Farshid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

farshid.s@umsu.ac.ir

Settings and conduct

This study will be conducted in patients undergoing PCNL in Urmia Imam Khomeini Hospital. Patients will be flushed with a cold or warm solution during PCNL. The patient and the researcher who will be evaluating the outcomes will be blind to the allocation of patients into two groups.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

In this study, 50 patients between 18 and 60 years old undergoing PCNL will be included. Patients with kidney stones with a diameter of more than 2-3 cm, stones resistant to lithotripsy with extracorporeal shock wave, proximal ureter stones with a diameter of more than 1.5 cm, and diverticular stones will not be included in the study.

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-20, 1403/02/31

Intervention groups

Patients in one group will be washed with cold washing solution (20-24°C) and in the other group will be washed with warm solution (25-29°C) during PCNL.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Stone free rate; duration of surgery; complications; hypothermia

Trial completion date

empty

General information

Scientific title

Investigating the effect of normal saline irrigation temperature on surgical outcomes of patients undergoing percutaneous nephrolithotomy

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180625040232N11**

Registration date: **2023-10-27, 1402/08/05**

Public title

Investigating the effect of normal saline irrigation temperature in patients undergoing percutaneous

nephrolithotomy

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with kidney stones with a diameter of more than 2-3 cm
Patients with stones resistant to extracorporeal shock wave lithotripsy
Patients with proximal ureter stones with a diameter of more than 1.5 cm
Diverticular stones
Age between 18 and 60 years

Exclusion criteria:

Coagulation disorders
Severe heart failure

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to one of the hot or cold wash solution groups using computer-generated numbers produced by the Random allocation software. Thus, in this software, the number of groups and the total sample size will be entered, and then the "randomization" will be implemented in the block section. Then, the computer-generated number list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups. Thus, the randomization process will continue until the final sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blind to the allocation of patients into two groups. Washing process will be performed during percutaneous nephrolithotomy (PCNL) by a urologist (other than the outcome assessor) and finally the name of groups will be encoded with the letters A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini University hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2023-09-13, 1402/06/22

Ethics committee reference number

IR.UMSU.HIMAM.REC.1402.069

Health conditions studied

1

Description of health condition studied

Kidney stone

ICD-10 code

GB90

ICD-10 code description

Certain specified disorders of kidney or ureter

Primary outcomes

1

Description

Stone free rate

Timepoint

Second day after surgery

Method of measurement

Plain abdominal radiography

2

Description

Duration of surgery

Timepoint

Time taken for PCNL

Method of measurement

Minute

3

Description

Complications

Timepoint

Until the second day after surgery

Method of measurement

Physical examination

4

Description

Hypothermia (axillary temperature below 35°C)

Timepoint

Until the second day after surgery

Method of measurement

Thermometer

Secondary outcomes

1

Description

Length of hospitalization

Timepoint

Length of hospitalization

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: Patients in one group will be washed with cold washing solution (20-24°C) during PCNL.

Category

Other

2

Description

Intervention group: Patients in the other group will be washed with warm solution (25-29°C) during PCNL.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Saman Farshid

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57154-89397

Phone

+98 44 3345 7286

Email

farshid.s@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

Street address

Urmia University of Medical Sciences, Resalat Ave, Jahad Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 3009

Email

gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saman Farshid

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Phone

+98 44 3345 7286

Email

farshid.s@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saman Farshid

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Phone

+98 44 3345 7286

Email

farshid.s@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saman Farshid

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd,
Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Phone

+98 44 3345 7286

Email

farshid.s@umsu.ac.ir

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

En Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

The results will be published as an article and the data will not be published.

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

By email address of the corresponding author:farshid.s@umsu.ac.ir

Comments