

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A new washing protocol to sterilize the urinary system during percutaneous nephrolithotomy surgery

Protocol summary

Study aim

A new equipment protocol for sterilizing the infection system during PCNL percutaneous nephrolithotomy surgery

Design

The present study is a single-blind randomized clinical trial.

Settings and conduct

This clinical trial will be conducted in Sina Hospital on 50 patients. The patients will be divided into two groups: sterilization of the disease operating system during percutaneous nephrolithotomy surgery with 10cc of betadine 7.5 and sterilization of the infection system during percutaneous nephrolithotomy surgery with sterile water. The patient will not know which group they will be placed in. Also, the urology fellowship assistant will do betadine injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with indications for percutaneous nephrolithotomy surgery, Consent to participate in the study. Exclusion criteria: Immunocompromised patients, Taking drugs that cause immunodeficiency, Patients with a family history of thyroid problems.

Intervention groups

Intervention group 1: Urinary system sterilization during surgery with 10cc of 7.5% betadine solution (Povidoneiodine solution 10% PEJHAN CHEMI 250ml), Once during washing. Intervention group 2: Urinary system sterilization during surgery with 10cc sterile water, (Sterile water, free of DNase and RNase, Acell Teb Rad MED), Once during washing.

Main outcome variables

post-surgical infections

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048625N3**

Registration date: **2024-02-05, 1402/11/16**

Registration timing: **prospective**

Last update: **2024-02-05, 1402/11/16**

Update count: **0**

Registration date

2024-02-05, 1402/11/16

Registrant information

Name

seyed reza hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

Email address

srhoseini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-13, 1403/01/25

Expected recruitment end date

2025-03-10, 1403/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A new washing protocol to sterilize the urinary system during percutaneous nephrolithotomy surgery

Public title

A new washing protocol to sterilize the urinary system

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with indications for percutaneous nephrolithotomy surgery Consent to participate in the study

Exclusion criteria:

Immunocompromised patients Taking drugs that cause immunodeficiency Patients with a family history of thyroid problems

Age

From **17 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a single-blind, randomized clinical trial study. After random sequencing by the methodologist using the sealed envelope online site, the constructed sequence will be provided to a technician outside the research team. Blocks of four (A or B) are placed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a single-blind clinical trial study in which the patients are not informed about the type of intervention. The patient does not know whether he is in the intervention or control group due to being unconscious, and he cannot be informed about it in any way after the surgery.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Sina Hospital

Street address

Room 206, Ethics Committee Office, Second Floor,

Administrative Building, Sina Hospital, Imam Khomeini Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2022-10-23, 1401/08/01

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1401.075

Health conditions studied

1

Description of health condition studied

kidney stones

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

Post-surgical infections

Timepoint

24 and 48 hours after surgery

Method of measurement

Blood culture, urine culture, ESR, CRP, CBC, and body temperature measurement

Secondary outcomes

1

Description

Sodium measurement

Timepoint

24 and 48 hours after the operation

Method of measurement

Biochemical test-Sodium assay kit

2

Description

Potassium measurement

Timepoint

24 and 48 hours after the operation

Method of measurement

Biochemical test-Potassium assay kit

3

Description

Chloride measurement

Timepoint

24 and 48 hours after the operation

Method of measurement

Biochemical test-Chlorine test kit

Intervention groups

1

Description

Intervention group: Urinary system sterilization during percutaneous nephrolithotomy surgery with 10cc of 7.5% betadine solution (Povidonolodine solution 10% PEJHAN CHEMI 250ml), Once during washing.

Category

Treatment - Other

2

Description

Control group: Urinary system sterilization during percutaneous nephrolithotomy surgery with 10cc sterile water, (Sterile water, free of DNase and RNase, Acell Teb Rad MED), Once during washing.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Seyed Reza Hosseini

Street address

Urology Research Center, Sina Hospital, Hassan Abad

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<http://sinahospital.tums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Sixth Floor, Central University, Quds Ave., Keshavarz

Boulevard, Tehran

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information anonymously

When the data will become available and for how long

One year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Dr. Seyed Reza Hosseini 00982166348560

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

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

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