

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of tubeless percutaneous nephrolithotomy with and without suture on clinical outcomes: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of tubeless percutaneous nephrolithotomy with and without suture on clinical outcomes

Design

This is a single-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are a candidate for percutaneous nephrolithotomy referring to the Beheshti Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded so that the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 75 years, Candidate for percutaneous nephrolithotomy, Having stones more than one centimeter in diameter in the lower calyx, Having stones with a diameter of more than two centimeters in the upper and middle calyx and pelvis, Having stones more than one centimeter in diameter in the ureter, Exclusion criteria: History of previous surgery of renal stone

Intervention groups

Intervention group: Tubeless percutaneous nephrolithotomy without any suture on the location of surgery Control group: Tubeless percutaneous nephrolithotomy with one or two sutures on the location of surgery

Main outcome variables

Primary outcome: The amount of bleeding, leakage of urine from the surgical site, mean duration of hospitalization a Secondary outcome: Occurrence of abscess

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N396**

Registration date: **2021-05-15, 1400/02/25**

Registration timing: **prospective**

Last update: **2021-05-15, 1400/02/25**

Update count: **0**

Registration date

2021-05-15, 1400/02/25

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

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of tubeless percutaneous nephrolithotomy with and without suture on clinical outcomes: a single-blind randomized clinical trial

Public title

Effect of percutaneous nephrolithotomy with and without suture on clinical outcomes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 75 years, Candidate for percutaneous nephrolithotomy, Having stones more than one centimeter in diameter in the lower calyx, Having stones with a diameter of more than two centimeters in the upper and middle calyx and pelvis, Having stones more than one centimeter in diameter in the ureter,

Exclusion criteria:

History of previous surgery of renal stone

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare 50 sheets and write "intervention" on 25 sheets and "control" on others. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind.

Placebo

Not used

Assignment

Parallel

Other design features**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 and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.UMSHA.REC.1400.118

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**

The amount of bleeding during surgery

Timepoint

After end of surgery

Method of measurement

By counting the gases used

2**Description**

Leakage of urine from the surgical site

Timepoint

In the first 24 hours after surgery

Method of measurement

With clinical examination

3**Description**

Mean duration of hospitalization

Timepoint

After surgery

Method of measurement

Based on medical records

Secondary outcomes

1

Description

Occurrence of abscess at the surgical site

Timepoint

One month after surgery

Method of measurement

With clinical examination

Intervention groups

1

Description

Intervention group: Tubeless percutaneous nephrolithotomy without any suture on the location of surgery

Category

Treatment - Surgery

2

Description

Control group: Tubeless percutaneous nephrolithotomy with one or two sutures on the location of surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Abdorasul Dadabaev

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

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dadabaevrasul46@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abdorasul Dadabaev

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyyed Habibollah Moosavi Bahar

Position

Urologist

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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