Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 81 1838 0090

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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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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 Fahmideh Ave
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info.research@umsha.ac.ir
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

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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