

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of standard and tubeless intercostal percutaneous nephrolithotomy in patients with kidney stone: A single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess compare standard and tubeless intercostal percutaneous nephrolithotomy in patients with kidney stone. **Design:** A single blind randomized clinical trial. **Setting and conduct:** The eligible patients with kidney stone who will refer to Besat Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 18 to 65 years; stone with a diameter of more than 1 cm in the lower calyx; stone with a diameter of more than 2 cm in the upper and middle calyx and the pelvis; a stone with a diameter of more than 1 cm in the upper urethra. **Exclusion criteria:** A previous history of kidney surgery. **Intervention group:** Tubeless intercostal percutaneous nephrolithotomy. **Control group:** Standard intercostal percutaneous nephrolithotomy. **Primary outcome:** (a) amount of analgesic usage during 72 hours after surgery based on medical document; (b) duration of hospitalization after surgery based on medical document. **Secondary outcome:** Side effect of surgery (bleeding, damage to the kidney collecting system, spleen damage, colon damage, major vessel damage and pneumothorax) upon 72 hours after surgery through physical examination. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization. **Blinding:** Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706309014N172**
Registration date: **2017-07-02, 1396/04/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-02, 1396/04/11

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

2017-07-11, 1396/04/20

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of standard and tubeless intercostal percutaneous nephrolithotomy in patients with kidney stone: A single blind randomized clinical trial

Public title

Comparison of standard and tubeless intercostal percutaneous Kidney stone breaker in patients with kidney stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age of 18 to 65 years; stone with a diameter of more than 1 cm in the lower calyx; stone with a diameter of more than 2 cm in the upper and middle calyx and the pelvis; a stone with a diameter of more than 1 cm in the upper urethra. Exclusion criteria: A previous history of kidney surgery.

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: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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: Patients will be unaware of the type of intervention. Therefore, the trial will be run as single blind.

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
2017-06-17, 1396/03/27

Ethics committee reference number

IR.UMSHA.REC.1396.246

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 analgesic usage

Timepoint

during 72 hours after surgery

Method of measurement

based on medical document

2

Description

duration of hospitalization

Timepoint

after surgery upon discharge

Method of measurement

based on medical document

Secondary outcomes

1

Description

Side effect of surgery (bleeding, damage to the kidney collecting system, spleen damage, colon damage, major vessel damage and pneumothorax)

Timepoint

upon 72 hours after surgery

Method of measurement

through physical examination

Intervention groups

1

Description

Intervention group: Tubeless intercostal percutaneous nephrolithotomy.

Category

Treatment - Surgery

2

Description

Control group: Standard intercostal percutaneous nephrolithotomy.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Dr Mahdi Shahmirzaei

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources1**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 addressHamadan 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 sourceVice-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**

Besat Hospital

Full name of responsible person

Dr Mahdi Shahmirzaei

Position

Resident of Urology

Other areas of specialty/work**Street address**

Besat Hospital, Shahed Square

City

Hamadan

Postal code**Phone**

+98 81 3364 0030

Fax**Email**

msh1166@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Besat Hospital

Full name of responsible person

Dr Seyyed Habibollah Mosavi Bahar

Position

Urologist

Other areas of specialty/work**Street address**

Besat Hospital, Shahed Square

City

Hamadan

Postal code**Phone**

+98 81 3364 0030

Fax**Email**

shmbahar@umsha.ac.ir

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**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