

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the adverse effect of standard percutaneous nephrolithotomy versus & tubeless percutaneous nephrolithotomy in patients having kidney stone: a single blinded randomized controlled trial

Protocol summary

Summary

Objectives: To compare the adverse effect of standard percutaneous nephrolithotomy versus & Tubeless percutaneous nephrolithotomy in patients having kidney stone. Design: .a single blind randomized clinical trial. Setting and conduct: The eligible patients having kidney stone who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: Kidney stone; age of 18 to 80 years. Exclusion criteria: Indication of open surgery. Intervention group: Tubeless percutaneous nephrolithotomy. Control group: Standard percutaneous nephrolithotomy. Primary outcome: (a) hemoglobin before and 24 hours after intervention through laboratory testing; (b) hematoma 24 hours after intervention using sonography. Secondary outcome: Pain 24 hours after surgery using VAS. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: The patients will not be aware of the type of intervention. Therefore, the trial will be run as single blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611019014N129**
Registration date: **2016-11-18, 1395/08/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the adverse effect of standard percutaneous nephrolithotomy versus & tubeless percutaneous nephrolithotomy in patients having kidney stone: a single blinded randomized controlled trial

Public title

Comparison of the adverse effect of two methods of nephrolithotomy in patients having kidney stone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Kidney stone; age of 18 to 80 years.
Exclusion criteria: Indication of open surgery.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **58**

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: The patients will not be aware 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

2015-04-11, 1394/01/22

Ethics committee reference number

IR.UMSHA.REC.1394.37

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

hemoglobin

Timepoint

before and 24 hours after intervention

Method of measurement

through laboratory testing

2

Description

hematoma

Timepoint

24 hours after intervention

Method of measurement

using sonography

Secondary outcomes

1

Description

Pain

Timepoint

24 hours after surgery

Method of measurement

using VAS

Intervention groups

1

Description

Intervention group: Tubeless percutaneous nephrolithotomy.

Category

Treatment - Surgery

2

Description

Control group: Standard percutaneous nephrolithotomy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Mahmood Ebrahimi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice-chancellor for Research the 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 the 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**

Shahid Beheshti Hospital

Full name of responsible person

Dr Mahmood Ebrahimi

Position

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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