

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

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Sponsors / Funding sources

1**Sponsor****Name of organization / entity**

Vice-chancellor for Research the Technology,
Hamadan 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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Hamadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-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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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