Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison between classic percutaneous nephrolithotomy (PCNL) with nephrostomy free PCNL and tubeless PCNL on length of hospitalization and analgesic usage in patients with renal stones candidated for PCNL

Protocol summary

Summary

Objective: Comparison between classic percutaneous nephrolithotomy (PCNL) and nephrostomy free PCNL and tubeless PCNL on length of hospitalization and analgesic usage in patients with renal stones candidated for PCNL. Design: Randomized, not blinded, single center. Setting and Conduct: Patients will be divided in three groups randomly(senary batches): classic group, nephrostomy free group and tubeless group. Then length of hospitalization and amount of analgesic usage in patients will be checked. Participants including major eligibility criteria: Inclusion criteria: Each patient with renal stones who is referred to Shahid Beheshti hospital and candidated for percutaneous nephrolithotomy between 2012-2014. Exclusion criteria: Significant residual stones requiring Re-PCNL. Excessive bleeding during surgery and after surgery that nephrostomy tube will be fixed. Serious damage to the pyelocalyceal system that double J will be placed. Target sample size: Sixty patients Interventions: Using no nephrostomy and ureter catheter after surgery in the interventional groups Main outcome variables: Patient's hospital stay, Patient's analgesic usage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204169485N1**
Registration date: **2012-12-12, 1391/09/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-12, 1391/09/22

Registrant information

Name
Hamid Shayaninasab

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 81 1822 9571

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Hamedan University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between classic percutaneous nephrolithotomy (PCNL) with nephrostomy free PCNL and tubeless PCNL on length of hospitalization and analgesic usage in patients with renal stones candidated for PCNL

Public title

Comparison between kidney stone surgery through the skin, without nephrostomy tube method and without any tube method versus classic method.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Each patient with renal stones who is referred to Shahid Beheshti hospital and candidated for percutaneous nephrolithotomy between 2012-2014. Exclusion criteria: Significant residual stones requiring Re-PCNL. Excessive bleeding during surgery and after surgery that nephrostomy tube will be fixed. Serious damage to the pyelocalyceal system that double J will be placed.

Age

From **10 years** old to **90 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Hamedan University of Medical Sciences

Street address

Shahid Fahmide Blvd

City

Hamedan

Postal code

Approval date

2012-03-04, 1390/12/14

Ethics committee reference number

16/35/9/4583/د/پ

Health conditions studied

1

Description of health condition studied

Renal calculus

ICD-10 code

N20.0

ICD-10 code description

Nephrolithiasis NOS. Renal calculus or stone. Staghorn calculus. Stone in kidney.

Primary outcomes

1

Description

Patient's hospital stay

Timepoint

After discharge

Method of measurement

Length of hospitalization

2

Description

Patient's analgesic usage

Timepoint

After discharge

Method of measurement

Milligram amount of analgesic drug using by patient

Secondary outcomes

1

Description

Fever after 24 hours of surgery

Timepoint

24 hours after surgery

Method of measurement

By using thermometer

Intervention groups

1

Description

Control group: 1. Access to a suitable calyce 2. Dilatation 3. Intracorporeal lithotripsy 4. Fixing a nephrostomy tube 5. Placing a ureter catheter

Category

Treatment - Surgery

2

Description

Interventional group 1: All procedures are included like classic surgery except stage IV; Which means nephrostomy tube will not be fixed for these patients after surgery.

Category

Treatment - Surgery

3

Description

Interventional group 2: All procedures are included like classic surgery, except last two stages; Which means

patients will not have nephrostomy tube or ureter catheter after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamedan

Full name of responsible person

Hamid Shayani Nasab

Street address

Shahid Beheshti Hospital, Eram Blvd, Qaem Square, Shahid Fahmide Blvd

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Hamedan University of Medical Sciences

Full name of responsible person

Heydar Tavilaani

Street address

Vice Chancellor for Research, Hamedan University of Medical Sciences. Shahid Fahmide Blvd

City

Hamedan

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, Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Hamid Shayani Nasab

Position

Endourologist / Assistant Professor of University

Other areas of specialty/work

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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