

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1822 9571

##### Email address

shayaninasab\_h@umsha.ac.ir

#### 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 candidate 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/پ/د

## **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****Street address**

Medical Faculty, Hamedan University of Medical  
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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*