

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparative evaluation between ultrasound guided and fluoroscopy guided renal access in PCNL

#### Protocol summary

##### Summary

The aim of the study: Comparative evaluation between ultrasound guided and fluoroscopy guided renal access in PCNL Design of study: Randomized clinical trial, single blind, controlled with standard fluoroscopy, a single central. The study population: Inclusion criteria: each patient who is referred to the Shahid Beheshti hospital and that is candidate for surgical treatment of kidney stones through the skin between 2012-2014. Exclusion criteria: the underlying disease; renal failure; children under 15 years and severe obesity BMI> 35. Sample size: 64 patients in 2 groups of 32 persons. The intervention: access to the kidney using ultrasound. Time intervention: Before surgery. Study outcomes: reduced intraoperative complications and reduce the amount of radiation to the surgeon and patient

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201204229534N1**

Registration date: **2012-05-02, 1391/02/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-05-02, 1391/02/13

##### Registrant information

###### Name

Esmail Gol Mahmoudi

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1822 4864

###### Email address

e.golmahmoudi@umsha.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Hamedan University of Medical Sciences

###### Expected recruitment start date

2012-05-21, 1391/03/01

###### Expected recruitment end date

2013-01-10, 1391/10/21

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparative evaluation between ultrasound guided and fluoroscopy guided renal access in PCNL

###### Public title

Renal access with ultrasonic guide in renal stone operation

###### Purpose

Other

###### Inclusion/Exclusion criteria

Inclusion criteria: Each patient who is referred to the Shahid Beheshti hospital and that is candidate for surgical treatment of kidney stones through the skin between 2012-2014. Exclusion criteria: The underlying disease; Renal failure; Children under 15 years and Severe obesity BMI> 35.

###### Age

From **15 years** old to **149 years** old

###### Gender

Both

###### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 64

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Hamedan University of Medical Sciences

##### Street address

Hamedan University of Medical Sciences. Mahdiye st

##### City

Hamedan

##### Postal code

6517838736

#### Approval date

2012-01-05, 1390/10/15

#### Ethics committee reference number

16/35/9/3587/پ

## Health conditions studied

### 1

#### Description of health condition studied

Calculus of kidney

#### ICD-10 code

N20.0

#### ICD-10 code description

Nephrolithiasis NOS

## Primary outcomes

### 1

#### Description

Reduce the amount of radiation to the surgeon

#### Timepoint

During the intervention

#### Method of measurement

Seconds, using a stopwatch

### 2

#### Description

Reduce the amount of radiation to the patient

#### Timepoint

During the intervention

#### Method of measurement

Seconds, using a stopwatch

### 3

#### Description

Reduce operating costs

#### Timepoint

After the operation

#### Method of measurement

The operation cost

### 4

#### Description

Reduce intraoperative complications

#### Timepoint

After the operation

#### Method of measurement

Surgeon's idea

## Secondary outcomes

### 1

#### Description

Ultrasounds failure

#### Timepoint

During the operation

#### Method of measurement

Surgeon's idea

## Intervention groups

### 1

#### Description

Intervention group: Patient is positioned in prone situation; Then an ultrasound is performed to see the position of the calices and stones in the kidney and also large vesseles. With the nephrostomy needle under the ultrasound guidance, access to appropriate Calice will be done. Doppler ultrasound exam can help to prevent damage to large vessels.

#### Category

Other

### 2

#### Description

Control group: With the standard methods and with fluoroscopic assistance caliceal access will be achieved.

#### Category

Other

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Hamedans Shahid Beheshti hospital  
**Full name of responsible person**  
**Street address**  
**City**  
Hamedan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Heydar Tavilaani  
**Street address**  
Vice chancellor for research and Technology.  
Hamedan University of Medical Sciences. Mahdiye st  
**City**  
Hamedan

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

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  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Medical Student / Student  
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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*