

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

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Name of organization / entity

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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
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Vice chancellor for research and Technology.
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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

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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