Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

An assessment of blind PCNL outcomes and the related effective factors and a comparison of the outcomes with the fluoroscopic-guided PCNL

Protocol summary

Summary

The purpose of the study: The purpose of the study is assessing the outcome of blind PCNL and its related effective factors, and then, making a comparison with fluoroscopic-guided PCNL. The main inclusion criteria is presence of Stag-horn renal calculus and the main exclusion criteria is presence of Blood coagulation disorders. We will study 100 patients with kidney stones, who are referred to Shohadaye Tajrish Hospital and are candidates for PCNL. In order to carry out this study, patients will be randomly divided into two equal groups. Blind PCNL in one group and fluoroscopic-guided PCNL in another group will be carried out. Blind PCNL through anatomic landmark, namely lumbar notch, will be carried out. An 18-gauge needle will be inserted with an angle of 30 degrees through skin in the notch area below the 12th rib and will be advanced to the depth of 3-4 cm until it arrives at calyx. The background variables and demographic information will be recorded for each patient. At the end of the operation, KUB and sonography are performed to determine the urinary residue. In addition, in blind PCNL, all cases of punctures and the access locations will be determined by fluoroscopy. Moreover, puncture numbers will be calculated at the end of surgery and surgery complications like hematoma will be determined by sonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803121267N9**
Registration date: **2009-08-17, 1388/05/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-08-17, 1388/05/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center (UNRC), Shahid Beheshti University,

Expected recruitment start date

2007-02-20, 1385/12/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An assessment of blind PCNL outcomes and the related effective factors and a comparison of the outcomes with the fluoroscopic-guided PCNL

Public title

An assessment of blind PCNL outcomes and the related effective factors and a comparison of the outcomes with the fluoroscopic-guided PCNL

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of stag-horn renal calculus, caliceal stone with hydronephrosis, or impacted superior ureteral stone, written informed consent Exclusion criteria: More than 5 punctures, Presence of scar, previous operation, Skin infection at the surgical site, presence of blood coagulation disorders

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Urology and Nephrology Research Center (UNRC), Shahid Beheshti University, M.C.(SBMU), Tehran, I.

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1666677951

Approval date

2007-01-28, 1385/11/08

Ethics committee reference number

75

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

Number of punctures during PCNL

Timepoint

At the end of surgery

Method of measurement

observation

Secondary outcomes

1

Description

surgery complications such as hematoma

Timepoint

After surgery

Method of measurement

Sonography

Intervention groups

1

Description

Blind PCNL

Category

Treatment - Surgery

2

Description

PCNL with the guide of floroscopy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Labafi Nejad Hospital

Full name of responsible person

Street address

Labafi Nejad Hospital., 9th Boostan St., Pasdaran Ave., Tehran, I.R. Iran

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Sponsors / Funding sources

1

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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
Urology and Nephrology Research Center (UNRC), Shahid Beheshti University, M.C.(SBMU), Tehran, I.

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

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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