

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

Mojgan Borgheie

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

Email address

research@unrc.ir

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.

Street address
 UNRC, No.101,9th Boostan St., Pasdaran Ave., Tehran, I.R. Iran

City
 Tehran

Postal code
 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

City
 Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Shabnam Golshan

Street address

UNRC, No.101, Boostan 9th St., Pasdaran Ave.,
Tehran, I.R. Iran

City

Tehran

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**Contact****Name of organization / entity**

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

Full name of responsible person

Mojtaba Mohammadhosseini Ebne Chenari

Position

Resident

Other areas of specialty/work**Street address**

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

City

Tehran

Postal code

1666677951

Phone

+98 21 2256 7222

Fax

+98 212277954

Email

Research @unrc.ir

Web page address

www.unrc.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

Full name of responsible person

Hossein Karami

Position

Professor

Other areas of specialty/work**Street address**

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

City

Tehran

Postal code

1666677951

Phone

+98 21 2256 7222

Fax

+98 212277954

Email

Research @unrc.ir

Web page address

www.unrc.ir

Person responsible for updating data**Contact****Name of organization / entity**

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

Full name of responsible person

Mozhgan Borgheie

Position

MD

Other areas of specialty/work**Street address**

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

City

Tehran

Postal code

1666677951

Phone

+98 21 2256 7222

Fax

+98 212277954

Email

borgheie@unrc.ir

Web page address

www.unrc.ir

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