

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of therapeutic outcomes and complications of Overnight stay after Percutaneous Nephrolithotomy versus ordinary admission (3 days) in patients with renal stones: a randomized clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate the safety and result of Percutaneous NephroLithotomy (PCNL) during one night stay in patients undergoing PCNL surgery without complications

Design

Clinical trial with control group, with parallel groups, one blind, randomized

Settings and conduct

Patients undergoing Percutaneous NephroLithotomy PCNL in Tehran Labafinejad Hospital; single blind (the participant has no information about the time of discharge)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Acceptable anesthesia risk (ASA class < 3); No Single kidney or renal insufficiency; No Pyonephrosis or infected stone ; Insignificant residual stone (<5mm); No intra or postoperative complications; ≤ 1 unit blood transfusion during operation; < 3 units hemoglobin decrease in the next morning. Non inclusion Criteria: Taking anti-coagulants; Urinary tract infection; High creatinine.

Intervention groups

Group 1: patients will be discharged after removing foley catheter, ureteral stent, and nephrostomy tube after a night stay. In group 2 : the nephrostomy tube will be removed on the second postoperative day. The patient will be discharged on the third postoperative day after removing foley and ureteral stent.

Main outcome variables

Patients' non complicated discharge after one day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038115N1**

Registration date: **2018-05-25, 1397/03/04**

Registration timing: **retrospective**

Last update: **2018-05-25, 1397/03/04**

Update count: **0**

Registration date

2018-05-25, 1397/03/04

Registrant information

Name

Hormoz Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3221 2001

Email address

hormozkarami@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

2013-06-22, 1392/04/01

Actual recruitment end date

2014-01-05, 1392/10/15

Trial completion date

empty

Scientific title

Comparison of therapeutic outcomes and complications of Overnight stay after Percutaneous Nephrolithotomy versus ordinary admission (3 days) in patients with renal

stones: a randomized clinical trial

Public title

Comparison of therapeutic outcomes and complications of Overnight stay versus ordinary admission (3 days) after Percutaneous Nephrolithotomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Acceptable anesthesia risk (ASA class< 3) No Single kidney or renal insufficiency No Pyonephrosis or infected stone Insignificant residual stone (<5mm) No intra or postoperative complications ≤ 1 unit blood transfusion during operation < 3 units hemoglobin decrease in the next morning

Exclusion criteria:

Taking anti-coagulants UTI High creatinine

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **300**

Actual sample size reached: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method, the patients will be categorized into two groups. Each block contains 4 components named "A" and "B" representing two methods of interest. Based on the permutation of the words (A and B), six blocks are defined: 1: AABB 2: BBAA 3: ABBA 4: BAAB 5: ABAB 6: BABA. We will use numbers 1 to 6 from random numbers table to choose a block randomly. Numbers 0, 7, 8, and 9 will be ignored.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant has no information about the time of discharge

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

9th Boostan ,Pasdaran St,Tehran.

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2013-03-12, 1391/12/22

Ethics committee reference number

911222/4

Health conditions studied

1

Description of health condition studied

Stone Kidney

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

hemoglobin change

Timepoint

1-3 days

Method of measurement

Blood test

2

Description

creatinine change

Timepoint

1-3 days

Method of measurement

Blood test

3

Description

Patients' non complicated discharge after one day

Timepoint

1day

Method of measurement

Kidney, ureters and bladder x-ray (KUB), renal ultrasonography, checke hemoglobin (Hb) and creatinine (Cr), sodium and potassium .

Secondary outcomes

1

Description

Fever

Timepoint

first 24 hour
Method of measurement
thermometer

2

Description
residual stone
Timepoint
first 24 hour

Method of measurement
Sonography

Intervention groups

1

Description
Intervention group: In patients receiving general or spinal anesthesia, 5-French Ureteral Stent was placed on the affected side through cystoscopy. Then in dorsal lumbotomy position or supine position, pyelocaliceal system and stones were determined by contrast and fluoroscopy or ultrasonography, and a Chiba needle was passed into the selected calyces of the kidney. A guidewire was passed through the needle into the pelvis. Over the guidewire the dilators and then working element (26-30F) were placed, and by using normal saline solution as irrigating solution, 24 French nephroscope was passed inside Amplatz sheaths and the stone(s) were crushed by pneumatic lithotripsy and removed with grasper. Finally, a nephrostomy tube was fixed in the kidney. The size of the nephrostomy tube was 20-24F depending on bleeding during the procedure, extent of manipulation, and surgeon's preferences. If a considerable amount of the stone residue (>5mm) was observed on control fluoroscopy at the end of the procedure, the patient was excluded from the study. All the procedures were carried out by a surgeon. In group was discharged after extracting Foley catheter, ureter stent, and nephrostomy tub

Category
Treatment - Surgery

2

Description
Control group: In patients receiving general or spinal anesthesia, 5-French Ureteral Stent was placed on the affected side through cystoscopy. Then in dorsal lumbotomy position or supine position, pyelocaliceal system and stones were determined by contrast and fluoroscopy or ultrasonography, and a Chiba needle was passed into the selected calyces of the kidney. A guidewire was passed through the needle into the pelvis. Over the guidewire. The dilators and then working element (26-30F) were placed, and by using normal saline solution as irrigating solution, 24 French nephroscope was passed inside Amplatz sheaths and the stone(s) were crushed by pneumatic lithotripsy and removed with grasper. Finally, a nephrostomy tube was fixed in the kidney. The size of the nephrostomy tube

was 20-24F depending on bleeding during the procedure, extent of manipulation, and surgeon's preferences. If a considerable amount of the stone residue (>5mm) was observed on control fluoroscopy at the end of the procedure, the patient was excluded. The nephrostomy tube was removed on the second postoperative day. The patient was discharged on the third postoperative day after removing the Foley and the ureteral sten. Nephrostomy tube was extracted the day after surgery and the patient was discharged on the third postoperative day after extracting Foley catheter and ureter stent.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labafinejad Hospital
Full name of responsible person
Hormoz Karami
Street address
9th Boostan, Pasdaran St, Tehran Province
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2254 9039
Email
hormozkarami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Deputy Research and Technology
Street address
9th Boostan, Pasdaran St, Tehran Province
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2243 1920
Email
hormozkarami@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hormoz Karami

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

9th Boostan, Pasdaran St, Tehran Province

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2254 9039

Email

r.bandari2314@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hormoz Karami

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

9th Boostan, Pasdaran St, Tehran city

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2254 9039

Email

r.bandari2314@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Hormoz Karami

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

Street address

Department of Urology, Rahnamon Hospital, Farrokhi street, Yazd

City

Yazd

Province

Yazd

Postal code

1983969411

Phone

+98 35 3221 2001

Fax

Email

hormozkarami@ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available