Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 35 3221 2001

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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 dilatators 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 dilatators 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy 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

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

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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