Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison Outcome of Percutaneous Nephrolithotomy in Prone and Flank Position in Obese Patients

Protocol summary

Study aim

The aim of this study is to compare the two positions of prone and flank in PCNL surgery in people with a body mass index (BMI) above 30 kg/m2.

Design

Two arm parallel group randomised trial with outcome assessment of 70 patients with balanced block randomization in single center

Settings and conduct

PCNL will be carried out in prone or flank positions under general anesthesia by single surgical team. Cystoscopic ureteral catheterization and retrograde ureterographic fluoroscopy will help to find the pyelocalyceal anatomy. Puncture will be done with an 18 Gage needle with standard technique. A J tip wire will pass from the needle into the pyelocalyceal system Then dilatation wil be done to 30 Fr. Nephroscopy will be conducted by KARL STORZ Nephroscope (27092 AMA with 26 Fr. Sheat) and stones was fragmented by pneumatic lithotripter. After extraction of stones, nephroscopy site will be sutured and a ureteral catheter was left in ureter. Double j stent will be inserted in some cases due to indications. Ureteral and Foley catheters will be generally extracted after 48 hours and the patients were discharged.

Participants/Inclusion and exclusion criteria

Inclusion criteria was patient candidate for PCNL who had BMI above 30 kg/m2 and wanted to participate in the study. Exclusion criteria included untreated UTI, history of tumor in access tract, malignant renal tumor, and pregnancy.

Intervention groups

After completing the written consent form entered to study. Patients will be randomly assigned to one of the two groups, Flank or Prone position.

Main outcome variables

The stone free rate (SFR)stent stay day, hospital stay (day), surgery time (min), postoperative complications, creatinine, hemoglobin and hematocrit, and arterial blood gas (PH, HCO3 and PCO2) changes and acid-base hemostasis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049303N1**
Registration date: **2020-12-01, 1399/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-01, 1399/09/11**
Update count: **0**

Registration date

2020-12-01, 1399/09/11

Registrant information

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Name of organization / entity
Urology research center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison Outcome of Percutaneous Nephrolithotomy in Prone and Flank Position in Obese Patients

Public title
Comparison outcomes of percutaneous nephrolithotomy in prone and flank positions in obese patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patient candidate for PCNL who had BMI above 30 kg/m2
Exclusion criteria:
untreated UTI history of tumor in access tract malignant renal tumor pregnancy
Age
From **18 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be done by blocks of four by using randomization table and individual, without stratified randomization and without allocation concealment.
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
Tehran University of Medical sciences
Street address
7th daliri str. Zafar str. Shariati Str
City
Tehran
Province
Tehran
Postal code
1916665354
Approval date
2018-11-27, 1397/09/06
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.963

Health conditions studied

1

Description of health condition studied
Kidney stone
ICD-10 code
N20
ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Stone free rate
Timepoint
3 months after discharge
Method of measurement
Ct scan

2

Description
Hospital stay
Timepoint
7 days after intervention
Method of measurement
Hospital document

Secondary outcomes

empty

Intervention groups

1

Description
Firdt intervention group: flank position during percutaneous nephrolithotomy operation , in this operation renal stone is removed using nephroscope by floroscopy guidance without open surgery
Category
Treatment - Surgery

2

Description
Second intervention group: prone position during percutaneous nephrolithotomy operation , , in this operation renal stone is removed using nephroscope by floroscopy guidance without open surgery
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Seyed reza hosseini

Street address
Imam khomeini str.

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyed Reza Hosseini

Position
Full professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available
Title and more details about the data/document
Demographic data and outcome of Percutaneous Nephrolithotomy in Prone and Flank Position in Obese Patients
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
Academic people
Under which criteria data/document could be used
For clinical studies
From where data/document is obtainable
Dr yasseri Yasseri_2006@yahoo.com
What processes are involved for a request to access data/document
Send email to dr yasseri
Comments