

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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/m<sup>2</sup>.

##### 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 will 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/m<sup>2</sup> 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, HCO<sub>3</sub> and PCO<sub>2</sub>) 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

##### Name

Ali Mohammad Fakhr Yasseri

##### Name of organization / entity

Urology research center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2640 5257

##### Email address

yasseri\_2006@yahoo.com

##### 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/m<sup>2</sup>

**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**

First intervention group: flank position during percutaneous nephrolithotomy operation, in this operation renal stone is removed using nephroscope by fluoroscopy 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 fluoroscopy 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.

**City**

Tehran

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**Postal code**

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**Phone**

+98 21 6312 6000

**Email**

yasseri\_2006@yahoo.com

**Web page address**

<http://sinahospital.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed reza Hosseini

**Street address**

Enghelab str

**City**

Tehran

**Province**

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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

**Street address**

Sina hospital , imam khomeini str.

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

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**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Reza Hosseini

**Position**

Full professor

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Subspecialist

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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**