

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of total tubeless PCNL and tubeless PCNL on the outcomes of complete supine percutaneous nephrolithotomy (csPCNL): a single-blind randomized controlled trial

#### Protocol summary

##### Study aim

The effect of total tubeless PCNL and tubeless PCNL on the outcomes of complete supine percutaneous nephrolithotomy (csPCNL)

##### Design

A controlled, parallel-group, single-blind, randomized, phase 2-3 clinical trial on 78 patients. A randomizer software was used for randomization through the online sealed envelope program

##### Settings and conduct

The study will be performed in the urology ward and operating room of Razi Hospital in Rasht. This study is performed on 78 patients gradually and sequentially. Patients will be randomly divided into two groups: A (tubeless PCNL) and B (total tubeless PCNL). The surgeon does not know the patient group until the operation time. The analyst will also be unaware of the type of patient grouping.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 20 years Exclusion criteria: Patients with known metabolic diseases predisposed to stones, transplanted kidney stones, chronic renal failure, anatomical problems (ureteral stricture, duplicate ureter, single kidney, ....)

##### Intervention groups

Intervention group: In the total tubeless PCNL group, at the end of the procedure, no stent will be implanted for the patient and the patient will be completely tubeless. Control group: In the tubeless PCNL group, external stents are implanted for all patients after surgery.

##### Main outcome variables

Postoperative fever; postoperative hemoglobin; creatinine; postoperative infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090427001853N18**  
Registration date: **2022-08-21, 1401/05/30**  
Registration timing: **prospective**

Last update: **2022-08-21, 1401/05/30**

Update count: **0**

##### Registration date

2022-08-21, 1401/05/30

##### Registrant information

##### Name

Siavash Falahatkar

##### Name of organization / entity

Urology Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3352 5259

##### Email address

urc@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-09-06, 1401/06/15

##### Expected recruitment end date

2023-04-20, 1402/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of total tubeless PCNL and tubeless PCNL on the outcomes of complete supine percutaneous nephrolithotomy (csPCNL): a single-blind randomized controlled trial

**Public title**

The effect of total tubeless PCNL and tubeless PCNL on the outcomes of complete supine percutaneous nephrolithotomy

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 20 years Consent of patients to participate in the study

**Exclusion criteria:**

Metabolic disease known to predispose to stones  
Transplanted kidney stones Renal failure requiring chronic dialysis before surgery Anatomical problems (ureteral stricture, duplicate ureter, single kidney,...)  
Bleeding during surgery Occurrence of any surgical complications during the operation

**Age**

From **20 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **78**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with blocks of 4 through a table of random numbers with a ratio of 1 to 1 (in two groups A and B) using a randomizer through the sealed envelope online program

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

One of the researchers (urology resident) divides the patients into two groups A (tubeless PCNL) and B (total tubeless PCNL) based on the table prepared from random blocks. The surgeon does not know the patient group until the operation time. The analyst will also be unaware of the type of patient grouping. At the top of the checklist that is completed for each patient, the type of group (A or B) is mentioned.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Guilan University of Medical Sciences

**Street address**

Sardar Jangal street

**City**

Rasht

**Province**

Guilan

**Postal code**

41448-95655

**Approval date**

2022-07-20, 1401/04/29

**Ethics committee reference number**

IR.GUMS.REC.1401.250

**Health conditions studied****1****Description of health condition studied**

Postoperative complication of stent

**ICD-10 code**

Y40-Y59

**ICD-10 code description**

Drugs, medicaments and biological substances causing adverse effects in therapeutic use

**Primary outcomes****1****Description**

Postoperative fever

**Timepoint**

After the operation until the time of discharge

**Method of measurement**

Examination using a thermometer

**2****Description**

Postoperative infection

**Timepoint**

48 hours after surgery

**Method of measurement**

Lab test and urine culture

**3****Description**

Postoperative hemoglobin

**Timepoint**

24 hours after surgery

**Method of measurement**

Complete blood count (CBC) test

## 4

### Description

Postoperative creatinine

### Timepoint

24 hours after surgery

### Method of measurement

Blood test by kinetic Jaffe's and enzymatic method

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the total tubeless PCNL group, at the end of the procedure, no stent will be implanted for the patient and the patient will be completely tubeless.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: In the tubeless PCNL group, external stents are implanted for all patients after surgery.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital

##### Full name of responsible person

Siavash Falahatkar

##### Street address

Sardar-e-Jangal street

##### City

Rasht

##### Province

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urc1384@yahoo.com

##### Web page address

<https://urc.gums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

##### Full name of responsible person

Siavash Falahatkar

##### Street address

Sardar-e-Jangal Street

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##### Web page address

<https://urc.gums.ac.ir/>

#### Grant name

10506

#### Grant code / Reference number

32

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Urology Research Center, Guilan 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

Rasht University of Medical Sciences

##### Full name of responsible person

Shahab Aali

##### Position

Urology resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Urology

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Sardar-e-Jangal Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
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Siavash Falahatkar  
**Position**  
Professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Urology Research Center, Guilan University of Medical Sciences  
**Full name of responsible person**

Samaneh Esmaeili  
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Non-faculty researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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samaneh\_815@yahoo.com

## 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

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