

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of Laparoscopic Pyelolithotomy versus Percutaneous Nephrolithotomy for the Treatment of patients with Staghorn Kidney Stones ; a randomized clinical trial

#### Protocol summary

##### Study aim

1- Comparison of success rate of laparoscopy versus percutaneous surgery for kidney staghorn stone treatment

##### Design

Single-blinded randomized clinical trial consisting of 68 patients, will be divided into two arm parallel group , randomization will be done by random allocation software

##### Settings and conduct

This study is a parallel randomized clinical trial study. Patients with staghorn stones (which are one-piece or maximum two-piece with an extra-renal pelvis) who are candidates for elective surgery will enter in our study. Randomization will be done through permuted block randomization to be randomly divided into pyelolithotomy and PCNL groups. After completing the questionnaire, which includes the patient's demographic and paraclinical information, all variables examined during and after surgery will be completed according to questinnaire. Finally, the data will be entered in SPSS . the analyst is not aware about the type of patient group so this study is designed as Single Blind clinical trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with One-Piece or Two-piece Stag-Horn Stone with large Extra-Renal part Exclusion criteria : Patients who do not have consent for open surgery.

##### Intervention groups

34 patients will undergo laparoscopic pyelolithotomy and 34 patients will undergo percutaneous nephrolithotomy

##### Main outcome variables

stone free rate, serum creatinine before and after surgery, duration of surgery, rate of hemoglobin loss, duration of hospitalization, complications after surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180625040232N5**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **retrospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

##### Registration date

2020-08-06, 1399/05/16

##### Registrant information

##### Name

Saman Farshid

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 9931

##### Email address

farshid.s@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-03, 1399/01/15

##### Expected recruitment end date

2020-07-20, 1399/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of Laparoscopic Pyelolithotomy versus Percutaneous Nephrolithotomy for the Treatment of patients with Staghorn Kidney Stones ; a randomized clinical trial

## Public title

Evaluation of laparoscopic surgery success versus percutaneous surgery for kidney staghorn stone

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with One-Piece or Two-piece Stag-Horn Stone with large Extra-Renal part  
Absence Of active Urinary Tract Infection  
Absence Of coagulopathy  
Age 18-65 years old  
HB > 10 mg/dl  
ASA physical status classification 1 or 2

### Exclusion criteria:

Absence of consent for entering the study  
Absence of acceptance for the probability open surgery in each group of studies

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Data analyser

## Sample size

Target sample size: **68**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects; it means we will have 17 blocks. Then, within each block, subjects will be randomly assigned to laparoscopy or percutaneous procedure. Random assignment will be done using a random number table

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Given that the surgical technique should be reported to patients preoperatively , the researcher and patients participating in the study should be aware of the surgical technique, but the analyst is unaware of which patient belongs to which intervention group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center,Sh

##### Street address

No103,9th Boostan Eslami Ave.,Pasdaran Blvd,Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1666663111

#### Approval date

2019-06-20, 1398/03/30

#### Ethics committee reference number

IR.SBMU.UNRC.REC.1399.003

## Health conditions studied

### 1

#### Description of health condition studied

Calculus of kidney

#### ICD-10 code

N20.0

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

Stone Free Rate

#### Timepoint

During Surgery , 2weeks after surgery in outpatient visit at hospital clinic

#### Method of measurement

Checklist

## Secondary outcomes

### 1

#### Description

Pain severity after surgery

#### Timepoint

After surgery intervention during Admission

#### Method of measurement

According to Visual Analogue Scale Questionnaire

### 2

#### Description

Hemoglobin Drop After Surgery

#### Timepoint

Before and after surgery intervention

**Method of measurement**

CBC-Diff Test before and after surgery

**3**

**Description**

Surgery Time

**Timepoint**

During surgery intervention

**Method of measurement**

Recording the surgery time after anesthesia induction

**4**

**Description**

Post Operation Complication

**Timepoint**

Post operation complication

**Method of measurement**

Complication Check list

**5**

**Description**

Creatinine

**Timepoint**

Before and after surgery intervention

**Method of measurement**

Blood sampling

**6**

**Description**

Number of hospitalized day

**Timepoint**

Once on the discharge time

**Method of measurement**

Patient's file

**Intervention groups**

**1**

**Description**

Intervention group: Patients with one piece or maximum two piece Stag Horn Stone with extra renal pelvis who will undergo per-cutaneous nephrolithotomy

**Category**

Treatment - Surgery

**2**

**Description**

Intervention group: Patients with one piece or maximum two piece Stag Horn Stone with extra renal pelvis who will undergo laparoscopic Pyelolithotomy

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Labbafinejad Hospital

**Full name of responsible person**

Mohamad Hossein Soltani

**Street address**

Labbafinejad Hospital , Boostan 9 Paydarfard Ave.,Pasdaran Blvd , Tehran

**City**

تهران

**Province**

Tehran

**Postal code**

1666663111

**Phone**

+98 21 23601

**Email**

mhsoltani60@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shabnam Golshan

**Street address**

No 103, Boostan 9 Eslami Ave.,Pasdaran Blvd.,Tehran

**City**

تهران

**Province**

Tehran

**Postal code**

1666663111

**Phone**

+98 21 2256 7222

**Email**

Sh.Golshan2@gmail.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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saman Farshid

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Imam Khomeini Hospital , Ershad Blvd ,Urmia

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3345 7287

**Email**

samanf63@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saman Farshid

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

**Street address**

Imam Khomeini Hospital , Ershad Blvd ,Urmia

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Saman Farshid

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**City**

Urmia

**Province**

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**Phone**

+98 44 3345 7287

**Email**

Samanf63@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Any information without the need for patients' names will be available

**When the data will become available and for how long**

Six months after publication

**To whom data/document is available**

Faculty members of medical universities

**Under which criteria data/document could be used**

For research purposes

**From where data/document is obtainable**

Email to Dr. Saman Farshid farshid.s@umsu.ac.ir

**What processes are involved for a request to access data/document**

Email to Dr. Saman Farshid farshid.s@umsu.ac.ir

**Comments**