

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

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3345 7287

Email

samanf63@gmail.com

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

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

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