

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparing standard laparoscopy and mini laparoscopy for management of ureteral stone

Protocol summary

Summary

(1) Objective: Application of mini-laparoscopy for ureteral stone. (2) Design: We have designed a prospective randomized clinical trial to compare mini-laparoscopy and conventional laparoscopic surgery in patients with ureteral stones. (3) Setting and conduct: Patients with upper ureteral stone will be enrolled in the study and randomly will enter to standard or mini laparoscopic arms. Data will be collected in a prospective manner. (4) Participants including major eligibility criteria: Ureteral stones larger than 10 mm which failed to manage with medical expulsive therapy, ureteroscopy or shock wave lithotripsy will be included. Main exclusion criteria: patients with very high risk for general anaesthesia; coagulation disorders; stones at distal ureter; pyonephrosis; pregnancy. (5) Intervention: Patients will randomly assign to undergo standard or mini laparoscopic surgery using table of random numbers. Mini laparoscopic ureterolithotomy (MLU) defines as one 5-mm trocar for a 5-mm laparoscope and two or three 3-mm ports. At the other arm, standard laparoscopic ureterolithotomy (SLU) includes one 12-mm port for a 10-mm laparoscope and three 5-mm ports. Transperitoneal approach will be used for all patients in both arms. (6) Main outcome measures: Pain intensity will be registered by the patient using Numeric pain rating scale (NPRS) at several time intervals after surgery. To evaluate cosmetic results, Vancouver scar scale (VSS) will be completed by a third party for all patients 3 months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062334639N1**

Registration date: **2017-07-05, 1396/04/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-05, 1396/04/14

Registrant information

Name

Sepehr Hamedanchi

Name of organization / entity

Urmia university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 441 2600

Email address

sepehrhamedanchi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, Tehran, Iran

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-01-01, 1396/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing standard laparoscopy and mini laparoscopy for management of ureteral stone

Public title

Mini laparoscopy for ureteral stone

Purpose

Other

Inclusion/Exclusion criteria

Main inclusion criteria: ureteral stones larger than 10 mm which failed to manage with medical expulsive therapy, ureteroscopy or shock wave lithotripsy Main exclusion criteria: patients with very high risk for general anaesthesia; coagulation disorders; stones at distal ureter; pyonephrosis; pregnant patients

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics committee of Shahid Beheshti medical university

Street address

Shahid Bheshti university of medical sciences, Yaman street, Chamran highway

City

Tehran

Postal code

Approval date

2017-01-20, 1395/11/01

Ethics committee reference number

IR.SBMU.UNRC.1395.20

Health conditions studied

1

Description of health condition studied

ureteral stone

ICD-10 code

N20.1

ICD-10 code description

calculus of ureter

Primary outcomes

1

Description

cosmesis

Timepoint

3 months after surgery

Method of measurement

Vancouver scar scale

2

Description

pain

Timepoint

6, 12, 24, 48, 120 hours after surgery

Method of measurement

by the patient using Numeric pain rating scale

Secondary outcomes

1

Description

rehabilitation period

Timepoint

days to resume normal activity

Method of measurement

ask from patient

2

Description

complications

Timepoint

3 month

Method of measurement

lab and imaging

3

Description

operating time

Timepoint

during surgery

Method of measurement

clock

4

Description

bleeding

Timepoint

12 hours after surgery

Method of measurement

Hb level

Intervention groups

1

Description

Intervention: Mini laparoscopic ureterolithotomy will be done for patients with upper ureteral stone. Mini laparoscopic ureterolithotomy (MLU) defines as one 5-mm trocar for a 5-mm laparoscope and two or three 3-mm ports. Transperitoneal approach will be used for all patients. Colon will be mobilized medially and after releasing the ureter, incision will be made longitudinally over the stone site on the ureteral wall and stone will be pulled out. After placing a jj stent, ureteral opening will be repaired with separate stiches and stone will extract from camera port site

Category

Treatment - Surgery

2

Description

Control: standard laparoscopic ureterolithotomy (SLU) includes using one 12-mm port for a 10-mm laparoscope and three 5-mm ports. Colon will be mobilized medially and after releasing the ureter, incision will be made longitudinally over the stone site on the ureteral wall and stone will be pulled out. After placing a jj stent, ureteral opening will be repaired with separate stiches and stone will extract from camera port site

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejhad hospital

Full name of responsible person

Sepehr Hamedanchi

Street address

9th Boostan, Pasdaran street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti university of medical sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti university of medical sciences, Yaman street, Chamran highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti university of medical sciences

Full name of responsible person

Sepehr Hamedanchi

Position

Fellow of endourology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty