

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the Clinical Results and Complications of Retroperitoneal Laparoscopic Surgery of Pelvis and Ureter Stones and its Comparison with Open Surgery

Protocol summary

Summary

The aim of present study is to evaluate clinical results and complications of retroperitoneal laparoscopic surgery of pelvis and ureter stones and its comparison with open surgery. In a single center clinical trial study, 70 patients with pelvis and ureter stones who referred to Imam Reza Educational Medical Center of Tabriz University of Medical Sciences for doing lithotripsy surgery, will include the study and will evaluate. Patients will allocate in two groups based on the patient's desire. Inclusion criteria are middle and upper part of the ureter and the pelvic stone, and stone over 15 mm. Also exclusion criteria are multiple stones, and distal ureter stones. In first group patients (35 patients) will underwent laparoscopic retroperitoneal surgery and patients in the second group (35 patients) will underwent open stone surgery. Success in removing stones as the primary outcome variable and the incidence of postoperative complications as secondary outcome variables will be evaluate up to two weeks after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031312728N2**

Registration date: **2017-07-30, 1396/05/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-30, 1396/05/08

Registrant information

Name

Sakineh Hajebrahimi

Name of organization / entity

Urology Department, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7328

Email address

ebrahimis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University Of Medical Sciences.

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Clinical Results and Complications of Retroperitoneal Laparoscopic Surgery of Pelvis and Ureter Stones and its Comparison with Open Surgery

Public title

Retroperitoneal Laparoscopic Surgery of Pelvis and Ureter Stones and its Comparison with Open Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: middle and upper part of the ureter and the pelvic stone; stone over 15 mm. Exclusion

criteria: multiple stones; distal ureter stones.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Not 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 Tabriz University of Medical Sciences.

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Eastern Azerbaijan, Iran.

City

Tabriz

Postal code

Approval date

2017-04-24, 1396/02/04

Ethics committee reference number

IR.TBZMED.REC.1396.56

Health conditions studied

1

Description of health condition studied

Urinary stone

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Success in removing stones

Timepoint

During surgery

Method of measurement

Clinical evaluation

Secondary outcomes

1

Description

Surgical complications

Timepoint

Up to two weeks after surgery

Method of measurement

Clinical evaluation

Intervention groups

1

Description

In intervention group: Patients will undergo retroperitoneal laparoscopic surgery.

Category

Treatment - Surgery

2

Description

In control group: Patients will undergo open surgery of ureter and pelvic stones.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Reza Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Dr Rasoul Jafari

Street address

Imam-Reza Hospital of Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, Eastern Azerbaijan, Iran.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of

Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

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, Tabriz 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

Tabriz University of Medical Sciences.

Full name of responsible person

Dr Rasoul Jafari

Position

Resident of Urology

Other areas of specialty/work

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Faculty of Medicine, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

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ra.jafari009@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences.

Full name of responsible person

Dr Sakineh Hajebrahimi

Position

Subspecialty of Urology

Other areas of specialty/work

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Fax

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ebrahims@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

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