

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of efficacy and complications of Holmium Laser and Pneumatic Lithotripsy in treatment of adult patients with ureteral stones sized 6-20 millimeter

Protocol summary

Study aim

Comparison of efficacy and complications of Holmium Laser and Pneumatic Lithotripsy in treatment of adult patients with ureteral stones sized 6-20 millimeter

Design

In this non blinded randomized parallel clinical trial, 80 Patients are allocated randomly with double block allocation in one of the two groups (pneumatic or holmium laser lithotripsy) by help of sealed envelope and will receive the intervention of that group.

Settings and conduct

Patients referred to Shahid Beheshti hospital of Yasuj with ureteral stones less than 10 mm are divided into one of two groups. In the first group (pneumatic), ureteroscopy is performed in the lithotomy position, and after entering the ureter, litholapaxy is performed by standard method . In second group(holmium laser) similar to first group ureteroscopy is performed and lithotripsy will be done by laser fiber with standard method .Two weeks later, ultrasound is performed and the success of the treatment is measured by the absence of stones or the presence of residual stones. The duration of the operation and other complications are checked and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age more than18 years old , ureteral stone less than 20 millimeter,having informed consent
Exclusion criteria:Uncontrolled coagulopathy , Pregnancy, active urinary tract infection

Intervention groups

In the first group (pneumatic), after spinal or general anesthesia, ureteroscopy is performed in the lithotomy position, and after entering the ureter, litholapaxy is performed by standard method and if necessary, double J is placed. In second group(holmium laser) similar to first group after spinal or general anesthesia, ureteroscopy is performed and after observing stone lithotripsy will be

done by laser fiber with standard method

Main outcome variables

Change in the size and passage of stones ,operation time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N31**

Registration date: **2023-06-10, 1402/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of Holmium Laser and Pneumatic Lithotripsy in treatment of adult patients with ureteral stones sized 6-20 mililimeter

Public title

Holmium Laser versus Pneumatic Lithotripsy in treatment of patients with ureteral stones

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 15 years old suffering from ureteral stone stone size between 6-20mm. Having informed consent form

Exclusion criteria:

presence of coagulopathy pregnancy presence of active infection azotemia uncontrolled hypertension hypersensitivity to narcotic drugs any contraindication for anesthesia.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the law of random allocation, first 40 balls A = pneumatic and 40 balls B = holmium laser are placed through the conduit into a dark container and then the balls are randomly removed from the container without replacement and the created sequence is recorded. With the referral of each patient, one of the envelopes will be randomly selected by the patients and will be introduced as a study group. The stratification approach is not used. Concealment will not take place in the study.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

R.YUMS.REC.1402.017

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

ureteral stones

ICD-10 code

N20.9

ICD-10 code description

Urinary calculus, unspecified

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

passage of ureteral stones with sizes from 5 to 10 millimeters

Timepoint

Two weeks after start of treatment

Method of measurement

Perform KUB and sonography and patient report

Secondary outcomes**1****Description**

operation time

Timepoint

During operation

Method of measurement

With recording time from start of anesthesia till end of operation

Intervention groups

1

Description

Intervention group: In the first group (holmium laser) after spinal anesthesia, in lithotomy position ureteroscopy and lithotripsy will be done by laser fiber and if necessary double j will be inserted.

Category

Treatment - Surgery

2

Description

Control group: In the second group (pneumatic) after spinal anesthesia, in lithotomy position ureteroscopy and lithotripsy will be done by pneumatic lithotriptor and if necessary double j will be inserted.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Sadrolleh Mehrabi

Street address

Shahid Beheshti hospital, Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available