Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy and complications of transurethral lithotripsy (TUL) with Holmium laser versus extracorporeal shockwave lithotripsy (ESWL) in treatment of upper ureteral stones.

Protocol summary

Summary

Background & Aim: our goal in this study is comparing efficacy and complications of transurethral lithotripsy (TUL) with Holmium laser versus extracorporeal shockwave lithotripsy (ESWL) in the treatment of upper ureteral stones. Materials and Methods: Sixty patients with upper ureter stones with size of 5-15 mm that refer to Shahid Beheshti hospital of Yasuj that will be candidate for Lithotripsy after taking informed consent form and approval of ethics committee randomly assigned in two groups. In the first group ESWL will be done in supine position with Dornier Delta 2 machine with ultrasound Shock Waves by standard methods. After lithotripsy patients observed for two hours and patients' satisfaction will be checked by Beck scale. Then, in absence of any Complications patients will be discharged with medication order and outpatient follow up. In second groups after anesthesia by standard methods patients situated in lithotomy position and lithotripsy will be done with flexible ureteroscopy and Holmium laser with fluoroscopic guidance by standard methods. After operation, patients will be admitted and the next day in absence of any Complications they discharged with medication and outpatient follow up .in both groups two weeks later again patients visit and KUB with ultrasonography was done for efficacy of operation and complications and results again checked and data recorded and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501301323N8**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

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Sadrollah Mehrabi
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of transurethral lithotripsy (TUL) with Holmium laser versus extracorporeal shockwave lithotripsy (ESWL) in treatment of upper ureteral stones.

Public title

Holmium laser versus extracorporeal shockwave lithotripsy (ESWL) in treatment of upper ureteral stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 15 years old suffering from upper ureteral stone; stone size between 6-15 mm. Exclusion criteria: presence of coagulopathy; presence of neuropathy; stone size more than 15mm in ureter; presence of active infection; presence of azotemia; uncontrolled hypertension; hypersensitivity to narcotic drugs; pregnancy any contraindication for general anesthesia.

Age

From **15 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

Postal code

Approval date

2013-08-12, 1392/05/21

Ethics committee reference number

25/17/1391/پ

Health conditions studied

1

Description of health condition studied

Calculus of kidney and ureter

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Crushing of ureteral stones smaller than 15 milimeter

Timepoint

Two weeks after the lithotripsy and ureteroscopy

Method of measurement

KUB and Ultrasonography

Secondary outcomes

1

Description

Development of unwanted complications

Timepoint

During operation till two weeks later

Method of measurement

Observatin and examination and ultrasonography and imaging

Intervention groups

1

Description

Procedures will be done in supine position under fluoroscopic guidance by Dornier Delta 2 lithotriptor with standard technique in 12 kilovoltage power increased to 18 KV during 10 minutes until intolerance of patients or giving maximum shock of 3000.

Category

Treatment - Devices

2

Description

Lithotripsy in lithotomy position with flexible ureteroscope and Holmium laser lithotriptor.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Beheshti hospital

Full name of responsible person

Sadrollah Mehrabi

Street address
Shaheed Beheshi hospital, Montazeri street, Yasuj
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice chancellor
Full name of responsible person
Dr Mehdi Akbartabar
Street address
Mottahari street,Research vice chancelor, Yasuj University of Medical Sciences, ,
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research vice chancellor
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
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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