

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

###### 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

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 chancellor, 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****Name of organization / entity**Faculty of Medicine, Yasuj University of Medical  
Sciences**Full name of responsible person**

Sadrollah Mehrabi

**Position**

professor, Fellowship of endourology and laparoscopy

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**Faculty of medicine, Yasuj University of Medical  
Sciences**Full name of responsible person**

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**Position**Professor of urology department, Fellowship of  
endourology and laparoscopy**Other areas of specialty/work****Street address**

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**Fax****Email****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*