

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Comparative efficacy of Holmium laser with local anesthesia and transurethral resection of the bladder tumor (TURBT) in patients with non-muscle invasive

#### Protocol summary

##### Summary

In this randomized clinical trial 76 patients with Papillary bladder tumors (<3 cm) that has therapeutic action (including TuRBT, laser or intravesical chemotherapy) has been done for them and willing to participate in the study and to complete the consent form, discussed and careful history taken from patients at the first visit and complete clinical examination, blood test for creatinine, hemoglobin, PSA, Ca, P, LFT, urine analysis and urine cytology are. Aspanyal anesthesia or general anesthesia (depending on clinical condition and comorbidities) and Holmium laser bladder tumor with local anesthesia (injection of 20 mL of 2% lidocaine gel) are included. group external laser treatment and other therapies (such as TURBT, intravesical chemotherapy or radical cystectomy) will start for the patient. Webster bladder tumor mass of cold cup biopsy specimens and samples from TuRBT laser group is sent to pathology. The results of the duration of hospital stay and postoperative catheterization time, there hematuria and the amount of irrigation fluid used during surgery, duration of surgery, the number of reflex obteratur and perforation of the bladder, causing dysuria and frequency after practice, creating UTI and other complications after surgery and the rate of recurrence, the recurrence and progression of tumor stage and Grade 18 months, and complications and recurrence rates between the two groups at 1, 3, 6, 12 and 18 months after treatment review and compare

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701078146N18**

Registration date: **2017-03-12, 1395/12/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-03-12, 1395/12/22

##### Registrant information

###### Name

Mohammadreza Razaghi

###### Name of organization / entity

Laser application in medical sciences research center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2271 8021

###### Email address

laser.cntr@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative efficacy of Holmium laser with local anesthesia and transurethral resection of the bladder tumor (TURBT) in patients with non-muscle invasive

##### Public title

Comparative efficacy of Holmium laser with local

anesthesia and transurethral resection of the bladder tumor (TURBT) in patients with non-muscle invasive

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Papillary bladder tumors (<3 cm) that has therapeutic action (including TURBT, laser or intravesical chemotherapy) has been done for them and willing to participate in the study.

### **Age**

From **25 years** old to **75 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **76**

### **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**

Organizational committee of ethics in biomedical research Shahid Beheshti University of Medical Scie

##### **Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

##### **City**

Tehran

##### **Postal code**

##### **Approval date**

2015-08-23, 1394/06/01

##### **Ethics committee reference number**

IR.SBMU.RAM.REC.1394.157

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Bladder tumors

#### **ICD-10 code**

C67

#### **ICD-10 code description**

Malignant neoplasm of bladder

## **Primary outcomes**

### 1

#### **Description**

Recurrence and progression of stage & grade

#### **Timepoint**

1, 3, 6, 12 and 18 months after treatment

#### **Method of measurement**

Cystoscopy

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: TuRBT

#### **Category**

Other

### 2

#### **Description**

Intervention group: Holmium laser for patients holmium laser to perform laser treatment process and not a limitation of this method in tissue obtained by biopsy of the tumor cold enough for grading the probability of incomplete tumor grading will be explained further treatment delay

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shohadaye Tajrish Hospital

##### **Full name of responsible person**

##### **Street address**

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr. Afshin Zarghi

##### **Street address**

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo  
Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

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**

Laser Application Research Centre

**Full name of responsible person**

Mohammad Reza Razaghi ,MD

**Position**

Head of research center

**Other areas of specialty/work**

**Street address**

Shohada Hospital-Tajrish

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**Full name of responsible person**

Mohammad Reza Razaghi,MD

**Position**

Professor

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**Name of organization / entity**

Laser Application Research Centre

**Full name of responsible person**

Zahra Razaghi

**Position**

Research Expert

**Other areas of specialty/work**

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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*