

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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+98 21 2271 8021

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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

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
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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

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**Person responsible for scientific
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Zahra Razaghi

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Research Expert

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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