

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of Comparison between the Diode laser method and Transurethral resection of the prostate in patients suffering BPH

Protocol summary

Summary

Transurethral resection of the prostate is still the standard treatment of benign BPH but the surgical lasers recently introduced seem to offer the patient a very low perioperative complication rate, a short learning curve, and reduced perating time. A recently introduced high-powered diode laser (980nm) offers a simultaneous absorption in water and hemoglobin but is lacking clinical experience. In this clinical trial study, the feasibility, and postoperative outcome of vaporization of prostate by means of a diode laser were investigated and compared with Transurethral resection of the prostate as a gold standard treatment. One hundred patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia will include in this study. Patients will assign to two fifty-patient groups according to the method of surgical treatment: Transurethral resection of the prostate and high-powered diode laser (980nm). All patients underwent physical examination and evaluation of symptoms according to the International Prostate Symptoms Score (IPSS). Blood tests included blood cell count, serum chemistry, serum prostate-specific antigen (PSA), and urine analysis. Additionally, post-void residual urine volume (PVR) and the peak urinary flow rate (Qmax) will measure. Prostate size assesse by transrectal ultra-sound (TRUS). Demographic characteristics, the duration of the operation, the changes in hemoglobin and serum sodium, the complications, the hospitalization period and the duration of indwelling catheter compare between the two aforesaid groups.

General information

Acronym

Diode laser & Transurethral resection of the prostate

IRCT registration information

IRCT registration number: **IRCT201202138146N3**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

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

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

laser application in medical sciences research center, shahid beheshti university of medical sciences.

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Comparison between the Diode laser method and Transurethral resection of the prostate in patients suffering BPH

Public title

comparison Diode Laser and TURP treatment in BPH patient

Purpose

Treatment

Inclusion/Exclusion criteria

patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia in Shohada-e-Tajrish medical center

Age

From **50 years** old to **86 years** old

Gender

Male

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

100 patients with lower urinary tract symptoms suggestive of benign prostatic hyperplasia will include in this study. Using computer generated simple random tables in a 1:1 ratio, patients assigned to two fifty-patient groups according to the method of surgical treatment: TURP and high-powered diode laser (980nm).

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of shahid beheshti university medical sciences

Street address

Yaman st-Daneshjoo Blvd-Velenjak St

City

Tehran

Postal code**Approval date**

2010-04-18, 1389/01/29

Ethics committee reference number

Code 89

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

benign hyperplasia of prostate

ICD-10 code

D29.1

ICD-10 code description

benign neoplasms, of prostate

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

PSA

Timepoint

after surgery

Method of measurement

blood examine

2**Description**

Prostate volume

Timepoint

after surgery

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Transurethral resection of the prostate- Diode laser

Category

Treatment - Surgery

2**Description**

Transurethral resection of the prostate

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada-e-Tajrish Medical center

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Laser application in medical sciences research center

Full name of responsible person

Sadi Banar

Street address

Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Laser application in medical sciences research center

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 in medical sciences resaerch center

Full name of responsible person

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Position

resident of urology

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