Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity
Laser application in medical sciences research center
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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 assigne 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 committe 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 sugery
Method of measurement
blood examine

2

Description
Prostate volume
Timepoint
after sugery
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

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Person responsible for updating data

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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