Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of open prostatectomy method And classic TURP (Transurethral Resection of the Prostate) in patients with prostate benign hyperplasia

Protocol summary

Study aim

Comparison of two methods Open Prostatectomy and classic TURP (Transurethral Resection of the Prostate) in patients suffering from benign prostatic hyperplasia

Design

Clinical trials with control group, randomized, with parallel groups

Settings and conduct

100 patients with benign prostatic hyperplasia referred to the Urology Clinic of Shahid Rahnemoon Hospital of Yazd are enrolled according to inclusion and exclusion criteria and then assigned to two intervention and control groups by using sealed envelopes previously prepared and containing the name of the intervention - open surgery or TURP – in equal proportions. After Cystoscopy in Intervention group by open surgery and in Control group by TURP method Prostatectomy is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Classical indications of prostate surgery, Patients with prostate size between 30 and 70 grams, Completing informed consent form. Exclusion criteria: History of previous prostate surgery with high levels of PSA (Prostate Specific Antigen), Uncontrolled diabetes, History of CVA (cerebral vascular accident) and neurological diseases, Urinary tract obstruction, Addiction, Use of Neurological and Anticholinergic drugs.

Intervention groups

Intervention group: Prostatectomy is performed by open surgery. This procedure is usually performed with spinal anesthesia. Surgery with an incision in the bottom of abdomen done. After removing the prostate, for the control of postoperative bleeding, a catheter is usually inserted into the bladder through the abdomen.Control group: Prostatectomy is performed by TURP method. In this method, with spinal anesthesia, and by passing the camera into the Urethra, The part of the prostate that has caused the obstruction it completely clears and removes. The catheter is inserted for 24 hours after the operation.

Main outcome variables

Benign Prostatic Hyperplasia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180305038956N1**
Registration date: **2018-03-17, 1396/12/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-17, 1396/12/26**
Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Hormoz Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3626 0000

Email address

h.karami@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of open prostatectomy method And classic TURP (Transurethral Resection of the Prostate) in patients with prostate benign hyperplasia

Public title
Comparison of two prostatectomy methods
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The classical indications for prostate surgery Patients with prostate size between 30 and 70 grams Complete the informed consent form by the patient
Exclusion criteria:
Previous prostate surgery with high PSA (Prostate Specific Antigen) Levels Uncontrolled diabetes History of CVA (cerebral vascular accident) and neurological diseases Urinary tract obstruction Addiction Use of neurological and anticholinergic drugs
Age
From **50 years** old to **80 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using Sealed envelope
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
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Bahonar Sq,Yazd.
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2017-11-22, 1396/09/01
Ethics committee reference number
IR.SSU.REC.1396.143

Health conditions studied

1

Description of health condition studied
Benign prostate hyperplasia
ICD-10 code
N40
ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
Benign prostatic hyperplasia
Timepoint
One week after surgery, then one month, 3 months and 6 months after surgery
Method of measurement
The amount of Q-Max (Maximum urinary flow) in the uroflowmetry before and after the surgery

Secondary outcomes

1

Description
Bleeding
Timepoint
During surgery, up to a week later
Method of measurement
The rate of receiving blood during and after surgery, and expert examination

2

Description
Wound infection
Timepoint
One week after surgery, then up to 1 month after surgery
Method of measurement
Expert examination

3

Description
Duration of catheterization after surgery
Timepoint
1,3,7 days after surgery
Method of measurement
Expert examination

4

Description
Urethral stricture
Timepoint
1 week, 1 month and 3 months after surgery
Method of measurement
Expert examination and retrograde urethrography

Intervention groups

1

Description
Intervention group: At First, uroflowmetry is done for patients,Due to the size of the prostate and after cystoscopy, they undergo open prostatectomy on the same day. This is usually done with spinal anesthesia. Surgery with an incision at the bottom of the abdomen in the suprapubic area done. After removing the prostate, for the control of postoperative bleeding, a catheter is usually inserted into the bladder through the abdomen. After surgical procedure, Q-Max in uroflowmetry before and after surgery, urinary symptoms (obstruction and excitation) and postoperative complications such as bleeding, receiving blood during and after surgery, postoperative catheterization, wound infection , Urethral stricture and bladder neck and urinary retention in the period of one week, one month, three months and six months will be investigated.
Category
Treatment - Surgery

2

Description
Control group: At First, uroflowmetry is done for patients, Due to the size of the prostate and after cystoscopy, surgery for prostatectomy is performed by the TURP method (transurethral resection of the prostate). In this method, with spinal anesthesia, and by passing the camera into the urethral lumen, the part of the prostate that has caused the obstruction completely clears and removes. After surgical procedure, Q-Max in uroflowmetry before and after surgery, urinary symptoms (obstruction and excitation) and postoperative complications such as bleeding, receiving blood during and after surgery, postoperative catheterization, wound infection , Urethral stricture and bladder neck and urinary retention in the period of one week, one month, three months and six months will be investigated.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Doctor Rahnemoon Hospital
Full name of responsible person
Hormoz Karami
Street address
Shahid Doctor Rahnemoon Hospital, Farrokhi Street, Yazd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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ahmehrparvar@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Hormoz Karami

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
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Urologist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available