Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Comparative study on Uroflowmetry Index Improvement after Open Prostatectomy and Trans Urethral Resection of Prostate (TURP)

Protocol summary

Summary

Objective: A Comparative study on Uroflowmetry Index Improvement after Open Prostatectomy and Trans-Urethral Resection of Prostate (TURP) Material & methods: 70 patients with BPH, candidate for surgery, will randomly divided into two groups and each group will be operated by one of two methods. Uroflowmetry Before surgery and one month after the surgery will be performed and maximum and average urinary flow rate of each patient will be compared with himself and the whole groups will be compared. Inclusion criteria: 1 - BPH patients candidate for surgery 2 - All patients should allow for open surgery or TUR-P. Exclusion criteria: 1 - Prostate weight greater than 100 g or less than 40 grams 2 - Contraindications for TURP and open prostatectomy 3 – Urinary retention (Urethral catheterized patients). Intervention: Surgery will be performed with one of two methods. Outcome of study: 1 - Determination of mean urinary flow rate before and after attempting to open prostatectomy 2 - Determination of mean urinary flow rate before and after TUR-P 3 - Comparison of mean urinary flow rate changes in both groups 4 - Determination of prostate weight based on ultrasound before surgery 5 - Determination of sample weight removed by surgery 6 – Determination of Uroflowmetry improvement based on prostate weight before surgery and weight of prostate tissue removed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101185641N1**
Registration date: **2011-05-31, 1390/03/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-05-31, 1390/03/10

Registrant information

Name
Seyed Habibollah Mousavi-bahar
Name of organization / entity
Hamedan University of Medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 1823 0829
Email address
shmbahar@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study on Uroflowmetry Index Improvement after Open Prostatectomy and Trans Urethral Resection of Prostate (TURP)

Public title

Comparing two surgical methods for Benign Prostatic Hyperplasia (BPH) treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients with BPH candidated for surgery 2- All patients should be able to treat by both of TURP or Open prostatectomy. Exclusion criteria: 1- Prostate with more than 100 or less than 40 gr weight in ultrasonography 2- Contraindication for TURP or Open prostatectomy 3- Unability for lithotomy positioning 4- Small and fibrosed prostate 5- History of previous surgery for prostate 6- Prostatic carcinoma 7- Big bladder stone(more than 2 cm)

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamedan University of Medical Sciences

Street address
Fahmideh St.

City
Hamedan

Postal code
518/65178

Approval date
2011-04-06, 1390/01/17

Ethics committee reference number
6/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
Benign Prostatic Hypertrophy

ICD-10 code
N40

ICD-10 code description
Hyperplasia of prostate

Primary outcomes

1

Description
Mean urine flow rate

Timepoint
1 month

Method of measurement
Uroflowmetry

Secondary outcomes

empty

Intervention groups

1

Description
TURP

Category
Treatment - Surgery

2

Description
Open prostatectomy

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person

Street address

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Ali Ghaleiha

Street address
Fahmideh St.

City
Hemedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Seyed Habibollah Mousavi-bahar
Position
Chief of Urology Department, Associated Professor
Other areas of specialty/work
Street address
Urology ward, Shahid Beheshti hospital, Eram Blvd
City
Hamedan
Postal code
Phone
+98 81 1838 0283
Fax
+98 81 1838 1035
Email
shmbahar@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Seyed Habibollah Mousavi-bahar
Position
Chief of Urology Department, Associated Professor
Other areas of specialty/work
Street address
Urology ward, Shahid Beheshti hospital, Eram Blvd
City
Hamedan
Postal code
Phone
+98 81 1823 0829
Fax
+98 81 1838 1035
Email
shmbahar@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Seyed Habibollah Mousavi-bahar
Position
Chief of Urology Department, Associated Professor
Other areas of specialty/work
Street address
Urology Ward, Shahid Beheshti Hospital, Eram Blvd
City
Hamedan
Postal code
Phone
+98 81 1838 0283
Fax
+98 81 1838 1035
Email
shmbahar@yahoo.com
Web page address

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