

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Hamedan

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

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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*