

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of outcome and complications of open prostatectomy and TURP in treatment of medium- size hypertrophic prostate.

Protocol summary

Summary

The objective of this study was to compare open surgery with TURP in BPH cases. 200 patients with moderate size BPH who were candidates of surgery were randomly assigned to undergo open prostatectomy or TURP. Transrectal sonography, lab tests, International Prostate Symptom Score (IPSS) and uroflumetry were done for all patients at baseline and follow-up visits. Patients were visited one and 6 month after surgery and uroflumetry and systoscopy were done for them. The results were compared between study groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803181267N13**
Registration date: **2009-08-24, 1388/06/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-08-24, 1388/06/02

Registrant information

Name

Mojgan Borgheie

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.R.
Iran

Expected recruitment start date

2005-11-22, 1384/09/01

Expected recruitment end date

2007-11-22, 1386/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcome and complications of open prostatectomy and TURP in treatment of medium- size hypertrophic prostate.

Public title

Comparison of outcome and complications of open prostatectomy and TURP in treatment of medium- size hypertrophic prostate.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Prostate larger than normal and have one of these conditions:1 acute urinary retention more than one time 2.recurrent infection 3. recurrent hematuria 3. azotemia 4. dissatisfaction after treatment 5. absence of bladder stone or diverticule Exclusion Criteria: 1. bladder stone larger than 2 cm 2. weight of prostate more than 75 grams and less than 30 grams 3. resectable bladder diverticule 4.anclulosis and orthopedic problems 5. previous urethra problems 6. hernia 7. suspicious for PSA>4 or suspicious nodule in touch 8. DRE previous prostatectomy 9. others pathology results than BPH

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University

Street address

UNRC, No.101, 9th Boostan St., Pasdaran Ave.,
Tehran, I.R. Iran

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Approval date

2005-10-01, 1384/07/09

Ethics committee reference number

58

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

BPH

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

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

complication of surgery

Timepoint

during surgery ,1 and 6 month after surgery

Method of measurement

observation and phisical exam

2**Description**

urinary symptom

Timepoint

before surgery ,1 and 6 month after surgery

Method of measurement

International Prostate Symptom Score (IPSS)

Secondary outcomes**1****Description**

Prostate situation

Timepoint

After surgery

Method of measurement

systoscopy

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

TURP surgery

Category

Treatment - Surgery

2**Description**

open surgery

Category

Treatment - Surgery

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

Labafi Nejad Hospital

Full name of responsible person**Street address**

Labafi Nejad Hospital.,9th Boostan St., Pasdaran Ave.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.

Full name of responsible person

shabnam golshan

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Urology and Nephrology Research Center (UNRC),
Shahid Beheshti University, M.C.(SBMU), Tehran, I.

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**

Urology and Nephrology Research Center (UNRC),
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Position

Associate Professor

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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