Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of open prostatectomy versus transurethral prostatectomy on clinical and laboratory findings in patients with benign prostatic hyperplasia: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess open prostatectomy versus transurethral prostatectomy on clinical and laboratory findings in patients with benign prostatic hyperplasia. Design: a randomized clinical trial. Setting and conduct: The eligible patients with benign prostatic hyperplasia who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) having benign prostatic hyperplasia; (b) indication of prostatectomy. Exclusion criteria: (a) prostate greater than 100 gr or lower than 40 gr; (b) history of previous prostatic or urethral surgery; (c) having bladder stone. Intervention group: Prostate resection through transurethral prostatectomy. Control group: Prostate resection through open surgery prostatectomy. Primary outcome: (a) assessing the urine flow before and one month after intervention using uroflowmetry; (b) assessing incontinency before and one month after intervention by taking history; (c) assessing number of nocturia before and one month after intervention by taking history; (d) assessing impotency before and one month after intervention by taking history. Secondary outcome: (a) assessing prostatic specific antigen before and one month after intervention through laboratory test. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of groups of six. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512219014N87**
Registration date: **2016-01-03, 1394/10/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-01-03, 1394/10/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of open prostatectomy versus transurethral prostatectomy on clinical and laboratory findings in patients with benign prostatic hyperplasia: a randomized clinical trial

Public title
Effect of open prostatectomy versus transurethral prostatectomy on clinical and laboratory findings in patients with benign prostatic hyperplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (a) having benign prostatic hyperplasia; (b) indication of prostatectomy. Exclusion criteria: (a) prostate greater than 100 gr or lower than 40 gr; (b) history of previous prostatic or urethral surgery; (c) having bladder stone.
Age
From **40 years** old to **70 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of groups of six. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2015-10-17, 1394/07/25
Ethics committee reference number
IR.UMSHA.REC.1394.311

Health conditions studied

1

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

Primary outcomes

1

Description
assessing the urine flow
Timepoint
before and one month after intervention
Method of measurement
using uroflowmetry

2

Description
assessing incontinency
Timepoint
before and one month after intervention
Method of measurement
by taking history

3

Description
assessing number of nocturia
Timepoint
before and one month after intervention
Method of measurement
by taking history

4

Description
assessing impotency
Timepoint
before and one month after intervention
Method of measurement
by taking history

Secondary outcomes

1

Description
assessing prostatic specific antigen
Timepoint
before and one month after intervention
Method of measurement
through laboratory test

Intervention groups

1

Description
Prostate resection through transurethral prostatectomy
Category
Treatment - Surgery

2

Description
Prostate resection through open surgery prostatectomy
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Ehsan Ghaneei
Street address
Shahid Beheshti Hospital, Eram Ave.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Vice-chancellor for Research the Technology, Hamadan 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
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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