

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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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

Hamadan

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
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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

Shahid Beheshti Hospital

Full name of responsible person

Dr Ehsan Ghaneei

Position

Urology Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

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Urologist

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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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