Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Complications and Clinical Outcomes of Open Transvesical Prostatectomy With or Without Suprapubic Cystostomy in Patients With Benign Prostatic Hyperplasia

Protocol summary

Study aim

Comparison of clinical outcomes and postoperative complications between open transvesical prostatectomy with and without suprapubic cystostomy in patients with benign prostatic hyperplasia

Design

Randomized parallel-group single-blind (assessor and analyst) controlled trial with 114 participants (57 per group). Block randomization (block size 4) using SPSS, allocation concealment with opaque envelopes.

Settings and conduct

This study will be conducted at Shahid Beheshti Hospital, Hamadan, by a senior urologist. Outcome assessment and data analysis will be performed by blinded individuals, and patients will be followed for 30 days post-surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed BPH, prostate volume ≥80g, surgical clearance, informed consent. Exclusion: Prostate/bladder malignancy, coagulation disorders, non-discontinuable anticoagulants, active infection, prior prostate/bladder surgery, age >80 with high risk, refusal.

Intervention groups

Group 1 (Control): Open transvesical prostatectomy with suprapubic cystostomy. After bladder closure, a suprapubic catheter is inserted through a separate incision above the pubic symphysis, and continuous bladder irrigation is established through a three-way Foley catheter with outflow via the cystostomy. Group 2 (Intervention): Open transvesical prostatectomy without suprapubic cystostomy. Continuous bladder irrigation is established solely through a three-way Foley catheter, with both inflow and outflow through the same catheter.

Main outcome variables

Hemoglobin drop؛ blood transfusion؛ clot retention؛ early complications (fever, pain, dysuria)؛ cystostomy complications (infection, obstruction, displacement, leakage, hematoma)؛ hospital stay.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260428069197N2**
Registration date: **2026-08-18, 1405/05/27**
Registration timing: **prospective**

Last update: **2026-08-18, 1405/05/27**
Update count: **0**

Registration date

2026-08-18, 1405/05/27

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Complications and Clinical Outcomes of Open Transvesical Prostatectomy With or Without Suprapubic Cystostomy in Patients With Benign Prostatic Hyperplasia

Public title
Comparison of Open Prostatectomy With and Without Suprapubic Cystostomy in Benign Prostatic Hyperplasia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definite diagnosis of benign prostatic hyperplasia based on history, physical examination, ultrasonography, and urologist's opinionProstate volume of 80 grams or more based on preoperative ultrasonography and examinationHaving surgical clearance based on cardiology consultation and normal relevant laboratory tests Willingness to participate in the study and signing written informed consent

Exclusion criteria:
Presence of prostate or bladder malignancy based on preoperative diagnostic evaluations Presence of coagulation disorders Use of anticoagulant or antiplatelet drugs that cannot be safely discontinued before surgery Presence of active urinary tract infection or untreated systemic infection at the time of surgery History of any prior prostate or bladder surgery Age over 80 years with high-risk surgical conditions Patient's refusal to participate in the study

Age
To **80 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using block randomization with block sizes of four. The unit of randomization is at the individual level. The random sequence will be generated using SPSS statistical software version 26. For allocation concealment, opaque sealed envelopes with serial numbers will be used, which will be kept closed by an independent person until the time of surgery. After the patient is prepared for surgery and final eligibility is confirmed, the envelope will be opened and the patient will be allocated to one of the two study groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the surgical nature of the intervention, blinding of the surgeon, patient, clinical staff, and caregivers is not possible, as the patient and medical team become aware of the type of intervention due to the presence or absence of a suprapubic cystostomy tube. However, to reduce measurement bias in outcome assessment, two groups of individuals will be kept blinded: Outcome Assessor: The individual responsible for collecting data on postoperative outcomes (including hemoglobin drop, need for blood transfusion, clot-related urinary retention, fever, pain, and complications related to cystostomy) will be unaware of patients' group allocation. This person will have access to patients' medical records but will not know the group code, and outcomes will be recorded solely based on predefined clinical criteria. Data Analyst: The individual responsible for statistical analysis of the data will also be blinded to group allocation and will receive coded data (Code A and Code B). Decoding will only be performed after the final analysis is completed. All patients participating in the study have signed informed consent and are aware of their participation. Therefore, blinding does not imply lack of patient awareness about study participation and is conducted in full compliance with ethical standards.

Placebo
Not used

Assignment
Parallel

Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

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Shahid Fahmideh Blvd, Central Building of Hamadan University of Medical Sciences, 4th Floor, Vice-Chancellery for Research and Technology, Hamedan, Iran

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Approval date
2026-06-20, 1405/03/30

Ethics committee reference number
IR.UMSHA.REC.1405.218

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia
ICD-10 code
N40.1
ICD-10 code description
Enlarged prostate with lower urinary tract symptoms

Primary outcomes

1

Description
Postoperative hemoglobin drop
Timepoint
24 hours after surgery
Method of measurement
Measurement of blood hemoglobin (g/dL) before and 24 hours after surgery and calculation of the difference (preoperative Hb - postoperative Hb)

Secondary outcomes

1

Description
Need for postoperative blood transfusion
Timepoint
Up to 72 hours after surgery
Method of measurement
Documentation of receiving at least one unit of blood in medical records

2

Description
Clot-related urinary retention
Timepoint
Until discharge (maximum 7 days)
Method of measurement
Need for bedside irrigation or operating room evacuation and cystoscopy for clot evacuation

3

Description
Early postoperative complications (fever, pain, dysuria)
Timepoint
72 hours and 30 days after surgery
Method of measurement
Clinical examination and history; fever: axillary temperature ≥37.5°C; pain: requiring analgesia; dysuria: patient complaint

4

Description
Suprapubic cystostomy-related complications
Timepoint
Until discharge and 30 days after surgery
Method of measurement
Clinical examination and history including infection, obstruction, displacement, urine leakage, vascular injury, hematoma

5

Description
Length of hospital stay
Timepoint
At discharge
Method of measurement
Calculation of time interval between surgery day and discharge day (in days)

Intervention groups

1

Description
Intervention group: Open transvesical prostatectomy without suprapubic cystostomy. In this group, continuous bladder irrigation is established solely through a three-way Foley catheter, with both inflow and outflow through the same catheter.
Category
Treatment - Surgery

2

Description
Control group: Open transvesical prostatectomy with suprapubic cystostomy. After bladder closure, a suprapubic catheter is inserted through a separate incision above the pubic symphysis, and continuous bladder irrigation is established through a three-way Foley catheter with outflow via the cystostomy.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
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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
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Title: Data and Documentation Sharing Plan for the Clinical Trial Details: All de-identified individual participant data (IPD) will be shared along with the following documents: full study protocol, statistical analysis plan (SAP), informed consent form (ICF), clinical study report (CSR), analytic code (SPSS/R), and the data dictionary.

When the data will become available and for how long

Data and documents will be available from 3 months after publication of the primary article and will remain accessible for up to 5 years following publication.

To whom data/document is available

Researchers with a valid academic degree in medical sciences or epidemiology who provide a methodologically sound and approved research proposal for using the data.

Under which criteria data/document could be used

Purpose: Exclusively for secondary research and scientific analyses with academic purposes, with no commercial use. Conditions: 1. Receiving approval from the local ethics committee. 2. Signing a Data Use Agreement that includes a commitment to maintain confidentiality and not disclose participant identities. 3. Acknowledging the source of data in any resulting publications or presentations.

From where data/document is obtainable

Requests should be directed to the corresponding author of the article, Dr. Behzad Mohamad Soori. Email: behzad.soori@umsha.ac.ir

What processes are involved for a request to access data/document

1. The applicant submits a project summary (1-2 pages) including objectives, methodology, and proposed analyses, along with academic credentials and a confidentiality commitment, via email. 2. The request is reviewed scientifically and ethically by the corresponding author and an independent expert (if needed). 3. If approved, the applicant signs a Data Use Agreement. 4. After signing, de-identified data will be shared with the applicant through a secure platform (e.g., an encrypted sharing service). 5. The applicant commits to making no attempts to re-identify participants and to properly acknowledge the data source in any resulting publications.

Comments

Confidentiality: Patient identities will remain protected, and shared data will be completely de-identified and free of any direct identifiers (e.g., names, national IDs, dates of birth). Intellectual Property: Any use of the data must acknowledge the original source (the primary study authors), and commercial use of the data is strictly prohibited. Regulatory Compliance: This data sharing plan fully complies with the regulations of the Ethics Committee of Hamadan University of Medical Sciences and the ICMJE guidelines.