Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of incidence of painful bladder spasm between Pezzer catheter and 3-way Foley catheter used for suprapubic catheterization after open simple prostatectomy

Protocol summary

Study aim

Comparison the effect of three-way Pezzer and Foley catheters used for suprapubic catheterization in patients with open prostatectomy for painful bladder spasms

Design

This study is designed as a clinical trial with a randomized controlled group that will be performed as a single blind and single center with a sample size of 159. Sampling method and selection of samples for inclusion in the study will be non-randomly available and sequentially open among patients candidates for prostatectomy.

Settings and conduct

At Amir Al-Momenin Hospital in Tehran, after obtaining informed consent from patients undergoing open prostatectomy about the study, the urological surgeon used one of two types of Pezzer or Foley catheter for suprapubic catheterization and the patient is evaluated for postoperative bladder spasms by questionnaire.

Participants/Inclusion and exclusion criteria

Entry conditions: Patients with a diagnosis of LUTS / BPH who have undergone simple open prostatectomy as indicated. No-entry conditions: Atonic bladder, history of pelvic surgery (prostate or urinary tract), non-BPH-related disorders, history of coagulation disorder, history of opioid use

Intervention groups

According to the mentioned indications, after obtaining the consent of the research, patients are divided into two groups A and B, and in group A, a Pezzer suprapubic catheter is placed, and in group B, a three-way Foley catheter is placed as a suprapubic catheter. After surgery, patients are evaluated for the frequency and severity of painful bladder spasms by the researcher through a questionnaire and data are collected.

Main outcome variables

Determining the relationship between the severity and frequency of painful bladder spasms and the type of suprapubic catheter used after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220121053778N1**
Registration date: **2022-06-06, 1401/03/16**
Registration timing: **retrospective**

Last update: **2022-06-06, 1401/03/16**
Update count: **0**

Registration date

2022-06-06, 1401/03/16

Registrant information

Name

Mojtaba Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5595 3612

Email address

everlasting@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of incidence of painful bladder spasm between Pezzer catheter and 3-way Foley catheter used for suprapubic catheterization after open simple prostatectomy

Public title

The effect of suprapubic catheters on painful bladder spasms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with severe complications from enlarged prostate including: refractory urinary retention, persistent gross hematuria, bladder stones, recurrent UTI, evidence of upper or lower urinary tract dysfunction (such as azotemia / uremia), and urinary incontinence Overflow / urge type and prostate weighing more than 65-70 grams (estimated by DRE examination and ultrasound) are candidates for open prostatectomy and inclusion in the study. Patients with suspected prostate cancer (with increased PSA or abnormal DRE) can be candidates for open prostatectomy if the prostate biopsy test is negative.

Exclusion criteria:

Atonic bladder (confirmed by urodynamic study) Urinary disorders not related to BPH such as neurogenic bladder disorder History of pelvic surgery, including previous prostate or urethral surgery History of coagulation disorders Chronic pain condition History of opioid use

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In the implementation of this clinical trial intervention, which is a single blind study, participants (patients) are selected based on the inclusion criteria. After obtaining informed consent to conduct research in the intervention groups, they are classified and kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in research committee of Tehran Azad University of Medical Sciences

Street address

No. 50, Riazatkesh Alley, Deylaman jonoubi St, Rey, Tehran

City

ری

Province

Tehran

Postal code

1848834661

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.IAU.TMU.REC.1399.508

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

2

Description of health condition studied

Painful Bladder Spasms

ICD-10 code

N39.82

ICD-10 code description

Other specified disorders of bladder

3

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

Bladder Pain Score

Timepoint

Measurement of bladder pain score after surgery during the patient's hospitalization

Method of measurement

Bladder spasm symptom scale

2

Description

Bladder Pain Score

Timepoint

Measurement of bladder pain score after surgery during the patient's hospitalization

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Painkiller dosage

Timepoint

During Post operation hospitalization

Method of measurement

According to the documented prescription

Intervention groups

1

Description

Intervention group: a

Category

Treatment - Devices

2

Description

Intervention group: b

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Mojtaba Farahani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mehrdad Gholamzad

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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

Islamic Azad University

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mojtaba Farahani

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available