

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of ultrasonography and uroflowmetry index in diagnosis of bladder outlet obstruction in patients with lower urinary tract symptom due to benign prostatic hyperplasia

Protocol summary

Summary

This study aimed to compare ultrasonography and uroflowmetry index in recognition of bladder outlet obstruction due to benign prostatic hyperplasia. In this descriptive cross sectional study (diagnosis), 250 patients with lower urinary tract symptoms due to benign prostatic hyperplasia referred to the urology clinic of Razi Hospital in Rasht, will be enrolled. Patients with a history of surgery for prostate and urinary tract will be excluded. Patients' information including age, irritation and obstructive symptoms of bladder (dysuria, urinary frequency, daily, urgency of urination, nocturia, straining to urinate, incomplete emptying of the bladder, reducing the pressure and urine diameter, delay in starting the urine, intermittency), urinary incontinence and acute urinary retention in the form of a standard questionnaire (International Prostate Symptom Score (IPSS)) will be recorded. All patients will undergo ultrasonography and uroflowmetry in term of diagnosis of bladder outlet obstruction. Prostate volume; urinary residue; detrusor thickness and median lobes will be measured will be measured by transabdominal ultrasonography. Patients will place in three ranges in terms of maximum urinary flow rate (Qmax): Qmax of less than 10 ml per second (symptomatic bladder outlet obstruction), Qmax of less than 10 ml per second and greater than 15 ml per second (equivocal), Qmax greater than 15 ml per second (normal).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022326718N1**
Registration date: **2016-05-11, 1395/02/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-11, 1395/02/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2015-08-25, 1394/06/03

Expected recruitment end date

2016-08-24, 1395/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasonography and uroflowmetry index in diagnosis of bladder outlet obstruction in patients with lower urinary tract symptom due to benign prostatic hyperplasia

Public title

Comparison of ultrasonography and uroflowmetry in diagnosis of bladder outlet obstruction due to benign prostatic hyperplasia

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: patients presenting with lower urinary tract symptom (LUTS) due to benign prostate hyperplasia (BPH) Exclusion criteria: history of prostatitis; urinary tract surgery; trauma; Urethritis; urinary stone passage; Catheterization; abnormal prostate specific antigen (PSA) and digital rectal exam (DRE); BPH surgical criterias; Neurogenic bladder

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 250

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square

City

Rasht

Postal code

41938-93345

Approval date

2015-08-24, 1394/06/02

Ethics committee reference number

IR.GUMS.REC.1394.212

Health conditions studied

1

Description of health condition studied

Bladder outlet obstruction

ICD-10 code

N32.0

ICD-10 code description

Bladder-neck obstruction

Primary outcomes

1

Description

Prostate volume

Timepoint

During hospitalization

Method of measurement

Ultrasonography

2

Description

Urine residue

Timepoint

During hospitalization

Method of measurement

Ultrasonography

3

Description

Bladder wall thickness

Timepoint

During hospitalization

Method of measurement

Ultrasonography

4

Description

Intravesical protrusion of prostate

Timepoint

During hospitalization

Method of measurement

Ultrasonography

5

Description

Qmax

Timepoint

During hospitalization

Method of measurement

Uroflowmetry

6

Description

International Prostate Symptom Score

Timepoint

During hospitalization
Method of measurement
Based on a standard questionnaire with scores of 0 to 35

7

Description
Prostate specific antigen
Timepoint
During hospitalization
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Abdominal ultrasonography
Category
Diagnosis

2

Description
Uroflowmetry
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Sahand Omid (Resident)
Street address
Sardar Jangal Street, Razi hospital
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Center
Full name of responsible person
Dr. Siavsh Falahatkar
Street address
Sardar Jangal Street, Razi hospital, Urology Research Centre
City
Rasht
Grant name

10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Center
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

Contact

Name of organization / entity

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Full name of responsible person

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Position

Co worker/Resident

Other areas of specialty/work

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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