Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of intravesical injection of Botox with oral tamsulosin 0.4 mg in the treatment of lower urinary tract symptom disorders (LUTS) in patients with symptomatic benign prostatic hyperplasia (BPH).

Protocol summary

Study aim

Comparison of the effect of intravesical injection of Botox with oral tamsulosin 0.4 mg in the treatment of LUTS disorders in patients with symptomatic BPH.

Design

Clinical trial with intervention and control group, with parallel groups, randomized, on 40 patients. Blocking technique will be used for randomization.

Settings and conduct

In this clinical trial study, 40 people with benign prostatic hyperplasia with lower urinary tract symptoms who referred to Imam Khomeini Hospital in Ahvaz were randomly divided into 2 groups of 20 people, the target and control groups were injected with Botox in the area Bladder neck and tamsulosin receive 0.4 mg orally daily. Blinding is not possible and all the names and personal information of the patients will be coded during data collection and will remain completely confidential.

Participants/Inclusion and exclusion criteria

Men with benign prostatic hyperplasia who have lower urinary tract symptoms will be included in the study and people who are allergic to Botox will be excluded from the study.

Intervention groups

The intervention group includes patients with benign prostatic hyperplasia who will undergo botox injection in the bladder neck area. The comparison group includes patients with benign prostatic hyperplasia who will be treated with tamsulosin 0.4 mg orally daily.

Main outcome variables

Total Prostate Specific Antigen,International Prostate Symptom Score, Post-Void Residue, Prostate Volume, Voided Volume, maximum urinary flow rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240409061460N1**
Registration date: **2024-04-22, 1403/02/03**
Registration timing: **prospective**

Last update: **2024-04-22, 1403/02/03**
Update count: **0**

Registration date

2024-04-22, 1403/02/03

Registrant information

Name

Reyhaneh Rahnama

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3333 2368

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rahnama.reyhane93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of intravesical injection of Botox with oral tamsulosin 0.4 mg in the treatment of lower urinary tract symptom disorders (LUTS) in patients with symptomatic benign prostatic hyperplasia (BPH).

Public title
Comparison of bladder botox and tamsulosin tablets in the treatment of symptomatic benign prostatic hyperplasia (BPH) patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- Prostate volume more than 30 ml 2- Obtaining a score higher than 8 from the International Prostate Symptom Score (IPSS) 3- Serum level total prostate specific antigen (tPSA) less than 10ng/mL 4- maximum urinary flow rate (Qmax) less than 16 ml/s 5- Voided volume (VV) more than 150 ml

Exclusion criteria:
1- Having an active and recurrent urinary tract infection 2- History of previous prostatectomy 3- History of prostate cancer 4- Bladder or prostate stones 5- History of using phenylephrine, pseudoephedrine, imipramine, cholinergic, anticholinergic, estrogen, androgen and steroid since 4 weeks before the intervention 6- Biopsy from 6 weeks before the intervention 7- History of unstable angina pectoris, primary neurological disease that affects bladder function, such as multiple sclerosis, myasthenia gravis, Parkinson's 8- History of BoNT-A intraprostatic administration 9- Taking ASA, warfarin and NSAIDs from 6 days before the intervention 10- History of bladder sensitivity to BoNT-A

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation is done by block method. 5 blocks of 8 are used. In this way, the number of 5 blocks of 8 will be randomly extracted using WIN PEPI software. 8 compounds will be from two groups A (injection group) and group B (oral pill group).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address
Ahvaz Academic City - Vice-Chancellor for Research and Technology, Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz - ground floor

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2024-04-06, 1403/01/18

Ethics committee reference number
IR.AJUMS.REC.1403.006

Health conditions studied

1

Description of health condition studied
Benign prostatic hyperplasia

ICD-10 code
D29.1

ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
maximum urinary flow rate

Timepoint
Before and 3 months after the intervention

Method of measurement
Uroflowmetry test

2

Description
Total Prostate Specific Antigen

Timepoint
Before and 3 months after the intervention

Method of measurement
ELISA test on blood sample

3

Description

Prostate volume

Timepoint

Before and 3 months after the intervention

Method of measurement

Examination of ultrasound results

4

Description

Prostate symptoms

Timepoint

Before and 3 months after the intervention

Method of measurement

International Prostate Symptom Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will be injected with Botox in the bladder neck area.The way to inject Botox is that every 100 international units of Bo-A will be diluted in 2 ml of NT saline. The injection dose will be determined according to the prostate volume. For prostate volume less than 30 cc, between 30 and 60 cc and more than 60 cc, respectively, 100, 200 and 300 international units of BoNT-A under spinal anesthesia in the operation room will be injected in the neck area of the bladder.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will be treated with tamsulosin 0.4 mg orally once a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahvaz

Full name of responsible person

Dinyar Khazaeli

Street address

Golestan Blvd., Jundishapur University of Medical Sciences, Ahvaz, Faculty of Medicine

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakerkish

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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

Ahvaz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dinyar Khazaeli

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable