

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Clinical Efficacy of Transurethral Resection of the Prostate Combined with Oral Anticholinergics or Botulinum Toxin-A Injection to Treat Benign Prostatic Hyperplasia with Overactive Bladder, Randomized Clinical Trial Study

Protocol summary

after TURP at 1, 3 and 6 months after treatment

Study aim

Clinical Efficacy of TURP Combined with Oral Anticholinergics or Botulinum Toxin-A Injection to Treat Benign Prostatic Hyperplasia with Overactive Bladder

Design

The clinical trial had a control group with a parallel double-blind randomized phase 2 group on 42 patients Using computer random block are divided into two groups

Settings and conduct

The site is Shohada-e-Tajrish hospital. Group A is the patients who will be treated with sulfifenacin 5 mg daily one month after the TURP operation and if the symptoms of OAB persist.Group B will be patients who are injected with 300 units of Botox Dysport into the bladder detrusor muscles in the operating room at the same time as TURP, and at times 1, 3 and 6 all IPSS, urinary peak flow rate, residual urine volume after Urination is repeated for them.It is a double-blind study.

Participants/Inclusion and exclusion criteria

Inclusion 1.Obstructive symptoms of urinary obstruction defined by IPSS and enlarged prostate on DRE examination; 2. Satisfaction; 3. LUTS symptoms; 4. Approval of OAB and DO with biodynamics and study. Exit: 1. Patients with neurological diseases such; 2. Prostate or bladder cancer; 3. Bladder or prostate surgery in the past; 4. Dissatisfaction; 5.Hypersensitivity to sulifenacin or Botox.

Intervention groups

Patients who are eligible for the study are divided into two groups.In group A only solifenacin and in group B Botox injection were performed.

Main outcome variables

Determination and comparison of emergency incontinence, prostate volume, Q MAX, PVR in two treatment groups of botulinum and sulifenacin injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201225049827N1**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

seyedmohammad hosseininia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2226 3219

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Efficacy of Transurethral Resection of the Prostate Combined with Oral Anticholinergics or Botulinum Toxin-A Injection to Treat Benign Prostatic Hyperplasia with Overactive Bladder, Randomized Clinical Trial Study

Public title

Clinical Efficacy of Transurethral Resection of the Prostate Combined with Oral Anticholinergics or Botulinum Toxin-A Injection to Treat Benign Prostatic Hyperplasia with Overactive Bladder, Randomized Clinical Trial Study

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Obstructive symptoms of urinary obstruction defined by IPSS and enlarged prostate on DRE examination Consent to enter the study Existence of LUTS symptoms OAB and DO approval with biodynamics and Eurodynamics study

Exclusion criteria:

Patients with neurological diseases such as Parkinson's or stroke Prostate or bladder cancer People who have had bladder or prostate surgery in the past Dissatisfaction with enrollment Allergy to sulifenacin or Botox

Age

From **45 years** old to **84 years** old

Gender

Male

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are simply randomized by computer software at the time of admission by someone who is not aware of the interventions. They are divided into two groups. Then an envelope containing the type of intervention that is not clear will be given to them and they will be referred to the operating room.

Blinding (investigator's opinion)

Double blinded

Blinding description

The principal investigator, the health care personnel (physicians, nurses) who are responsible for patient care,

the data collectors, and those who evaluate the outcome are blind and unaware of the patient's treatment process. The Data Protection and Supervision Committee is not aware.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahrdari St. Shohada-E-Tajrish Hospital

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-09-27, 1398/07/05

Ethics committee reference number

IR.SBMU.UNRC.REC.1398.007

Health conditions studied**1****Description of health condition studied**

LUTS In patients with benign prostatic hyperplasia

ICD-10 code

Z87.4

ICD-10 code description

Personal history of diseases of genitourinary system

Primary outcomes**1****Description**

IPSS(International Prostate Score System) in two groups of botulinum and sulifenacin injection after TURP(Trans Urethral Resection Of Prostate) at 1, 3 and 6 months after treatment.

Timepoint

1, 3 and 6 months after transurethral resection of the prostate are checked

Method of measurement

Based on the International Index of Prostate Symptoms.

2

Description

Urgent incontinence in the two groups of botulinum and sulifenacin injections after TURP(International Prostate Score System) is performed at 1, 3 and 6 months after treatment

Timepoint

1, 3 and 6 months after transurethral resection of the prostate are checked

Method of measurement

It is done based on the patient's question

3

Description

Prostate volume in the two treatment groups of botulinum and sulifenacin injection after TURP(International Prostate Score System) is done at 1, 3 and 6 months after treatment

Timepoint

1, 3 and 6 months after transurethral resection of the prostate are checked

Method of measurement

It is done based on ultrasound

4

Description

PVR(Post Voiding Residue) is performed in two treatment groups botulinum and sulifenacin injection after TURP(International Prostate Score System) at 1, 3 and 6 months after treatment

Timepoint

1, 3 and 6 months after transurethral resection of the prostate are checked

Method of measurement

Based on Urodynamic test

5

Description

Q MAX(Q maximum) is administered in two treatment groups botulinum and sulifenacin injection after TURP(International Prostate Score System) at 1, 3 and 6 months after treatment

Timepoint

1, 3 and 6 months after transurethral resection of the prostate are checked

Method of measurement

Based on Urodynamic test

Secondary outcomes

empty

Intervention groups

1

Description

Disport Botox injection of 300 mg diluted with 10 cc of normal saline is injected into the bladder detrusor once

after transurethral resection of the prostate.

Category

Treatment - Drugs

2

Description

Control group: One month after transurethral resection of the prostate, they are treated with oral sulifenacin (vesicare 5mg) at a dose of 5 mg daily for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Seyed Mohammad Hosseinia

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Shahrdar St., Shohada Tajrish Hospital

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas Basiri

Street address

Pasdaran St., Ninth Park, next to Labbafinejad Hospital, No. 44

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Farzad Allame

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Seyed Mohammad Hosseininia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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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

Not applicable