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

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 after TURP at 1, 3 and 6 months after treatment

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
seyedmohammad_hosseininia@hotmail.com

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 Hosseininia

Street address
Shahrdar St., Shohada Tajrish Hospital

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2271 8003

Email
seyedmohammad_hosseininia@yahoo.com

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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2256 7222

Fax
+98 21 2256 7282

Email
info@unrc.ir

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
Street address
Shohada-e-Tajrish Hospital, Shahrdary Street. Tajrish Sq.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8003
Email
farzadallame@gmail.com

Person responsible for scientific 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
Street address
Shohada-e-Tajrish Hospital, Shahrdary Street. Tajrish Sq.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8003
Email
farzadallame@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mohammad Hosseininia
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Urology
Street address
Shohada-e-Tajrish Hospital, Shahrdary Street. Tajrish Sq.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2271 8003
Email
seyedmohammad_hosseininia@yahoo.com

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