

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

A clinical trial to compare the outcomes of transurethral resection of the prostate (TURP) and TURP plus Botox injection in patients with benign prostatic hyperplasia (BPH).

Protocol summary

Study aim

To compare the outcomes of transurethral resection of the prostate (TURP) and TURP plus Botox injection in benign prostatic hyperplasia (BPH) patients.

Design

In this pragmatic double-blind clinical trial, fifty patients with BPH were assigned into parallel groups using the table of random numbers in a community-based setting.

Settings and conduct

BPH patients at Imam Reza Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care provider and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range of 50-80 years, lower urinary tract symptoms resistant to standard medical treatment, international prostate symptom score (IPSS) of > 12, and prostate volume of >50 cm³ in ultrasound. Exclusion criteria: History of prostate surgery, prostate cancer, bleeding disorders, and incidence of acute urinary retention during the treatment.

Intervention groups

The intervention Group I will undergo TURP. The intervention Group II will concurrently receive TURP and 300 U intravenous Botox at 30 different locations.

Main outcome variables

Evaluation and comparison of clinical symptoms (e.g., dysuria, urinary frequency, and pelvic pain) based on the IPSS 3, 6, and 12 months after the intervention in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110306005981N3**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **prospective**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

Registration date

2018-12-25, 1397/10/04

Registrant information

Name

Maliheh Keshvari Shirvan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 1761 5063

Email address

keshvarim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the outcomes of transurethral resection of the prostate (TURP) and TURP plus Botox injection in patients with benign prostatic hyperplasia (BPH).

Public title

Treatment of transurethral resection of the prostate.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range of 50-80 years Lower urinary tract symptoms resistant to standard medical treatment international prostate symptom score (IPSS) of >12 prostate volume of >50 cm³ in ultrasound

Exclusion criteria:

History of prostate surgery Having prostate cancer Having bleeding disorders Incidence of acute urinary retention during the treatment

Age

From **50 years** old to **80 years** old

Gender

Male

Phase

2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Fifty BPH patients at the Imam Reza Hospital, Mashhad, Iran, were chosen. The participants were allocated into two groups of intervention using the table of random numbers based on computer programs.

Blinding (investigator's opinion)

Double blinded

Blinding description

BPH patients at Imam Reza Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care provider and data collector were blind to group assignment and the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah

Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2018-11-22, 1397/09/01

Ethics committee reference number

IR.MUMS.fm.REC.1396.317

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

Prostatic hyperplasia

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

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

Clinical symptoms (e.g., dysuria, urinary frequency, and pelvic pain)

Timepoint

3, 6, and 12 months after the intervention

Method of measurement

The international prognostic scoring system (IPSS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group I will receive of transurethral resection of the prostate treatment.

Category

Treatment - Surgery

2**Description**

Intervention group: The intervention group II will receive of transurethral resection of the prostate with 300 U intravenous Botox at 30 different locations.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Majid Chogani

Street address

Imam Reza Hospital, Imam Reza Square

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Postal code

9137913316

Phone

+98 51 1761 5063

Email

majidchokani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Mashhad

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Email

vcresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Maliheh Keshvari Shirvan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Chogani

Position

Residents

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Majid Chogani provides the analysis code to the applicants via email: majidchokani@yahoo.com

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments