

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Effects of intra-prostate botulinum toxin injection in patients with benign prostatic hyperplasia

#### Protocol summary

##### Study aim

Effects of intra-prostate botulinum toxin injection in patients with benign prostatic hyperplasia

##### Design

Randomized clinical trial without control group

##### Settings and conduct

This study was performed on 17 men with benign prostate enlargement at Mashhad Imam Reza Hospital. This method combines 200 units of botulinum toxin with 30 cc normal saline. then injected into the prostate through the urethra

##### Participants/Inclusion and exclusion criteria

Men with benign prostate hyperplasia who have irritable and obstructive symptoms. Men who have prostate cancer at the same time are excluded

##### Intervention groups

In this study, we evaluated the efficacy of intra-prostate Botox injection on urinary irritant and obstructive symptoms. Also changes in prostate size, urinary residual rate, and psa before and after injection were measured.

##### Main outcome variables

Determination of International Prostate Symptom Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190813044522N1**

Registration date: **2019-10-05, 1398/07/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-05, 1398/07/13**

Update count: **0**

##### Registration date

2019-10-05, 1398/07/13

#### Registrant information

##### Name

Amin Nowbahar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3858 3885

##### Email address

nobahara951@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2019-05-13, 1398/02/23

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Effects of intra-prostate botulinum toxin injection in patients with benign prostatic hyperplasia

#### Public title

The effect of intra-prostate Botox injection on the treatment of benign prostatic hyperplasia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All men with benign prostate hyperplasia who have been treated for the first time

##### Exclusion criteria:

The simultaneous presence of prostate cancer  
Concomitant active urinary tract infection Previous

history of prostate surgery Acute prostatitis

## Age

No age limit

## Gender

Male

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 17

## 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 mashhad University of Medical Sciences

##### Street address

Ebne sina

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

#### Approval date

2019-08-13, 1398/05/22

#### Ethics committee reference number

ir.mums.medical.rec.1397.521

## Health conditions studied

### 1

#### Description of health condition studied

Benign prostate hyperplasia

#### ICD-10 code

N40

#### ICD-10 code description

Enlarged prostate

## Primary outcomes

### 1

#### Description

The rate of improvement of irritable and obstructive symptoms of urine

#### Timepoint

Measurement of prostate size, psa and urinary residual volume, as well as irritable and obstructive symptoms of urine before and 3 and 9 months after injection

#### Method of measurement

A questionnaire containing patient information; International Prostate Symptom Score (IPSS); psa; and urinary residual

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 200 units of botulinum toxin in combination with 30 cc normal saline injected into the prostate through the urethra.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

imam reza hospital

##### Full name of responsible person

amin nowbahar

##### Street address

Ebne sina ave

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3858 3885

##### Email

nobahara951@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen tafaghodi

**Street address**

daneshgah ave;Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3858 3885

**Email**

nobahara951@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**

Amin nowbahar

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Ebne sina ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3858 3885

**Email**

nobahara951@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

salman soltani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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Ebne sina Ave

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

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**Email**

soltanis@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Amin Nowbahar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Ebne sina Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3858 3885

**Email**

nobahara951@mums.ac.ir

**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**

Undecided - It is not yet known if there will be a plan to make this available