Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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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 valume, 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen tafaghodi

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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
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
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Amin nowbahar
Position
resident
Latest degree
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Person responsible for updating data

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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

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