

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The assessment of the effect of injection of Botulinum toxin A (Transurethral method) on Benign Prostate Hyperplasia refractory to routine medical treatment in poor surgical candidates

Protocol summary

Summary

Benign prostate hyperplasia (BPH) is a major etiology of bladder outlet obstruction which can cause bothersome urinary symptoms. Although transurethral resection of prostate (TURP) is an effective and gold standard treatment for BPH, but its effect is not complete and almost 15-25% of patients don't have long term satisfactory outcomes after TURP. Botulinum toxin A (BoNT-A) reduces acetylcholine release from cholinergic terminals. Injection of BoNT-A in prostate causes apoptosis, inhibition of cellular proliferation and down regulation of $\alpha 1$ A receptors and seems that can reduce urinary symptoms. In this study 10 men with BPH refractory to routine medical treatment and not suitable for surgery will be selected. Data such as prostate volume, PSA, IPSS (International Prostatic Symptom Score), PVR and max flow rate will be recorded then BoNT-A injection in prostate will be done transurethrally. After 3 month variables will be recorded again and compared with previous data.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008174582N1**

Registration date: **2010-09-07, 1389/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-07, 1389/06/16

Registrant information

Name

Ali Hamidi Madani

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Guilan University of Medical Sciences

Expected recruitment start date

2010-06-06, 1389/03/16

Expected recruitment end date

2010-08-07, 1389/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the effect of injection of Botulinum toxin A (Transurethral method) on Benign Prostate Hyperplasia refractory to routine medical treatment in poor surgical candidates

Public title

The effect of injection of Botulinum toxin A on Benign Prostatic Hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male patients older than 50 years,

patients with BPH refractory to medical therapy and not suitable for surgery, IPSS (International Prostatic Symptom Score) ≥ 8 . Exclusion criteria: active UTI, previous history of prostate surgery, prostate cancer, acute prostatitis, simultaneous use of drugs such as: Amino glycosides, Cholinergics, Anticholinergics, Androgens, Estrogen, Steroids, history of allergy to BoNT-A, neurologic disease like Parkinson, Myasthenia Gravis, Multiple Sclerosis, history of allergy to BoNT.

Age

From **50 years** old to **149 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

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

Guilan University of Medical Sciences

Street address

Guilan University of Medical Science

City

Rasht

Postal code

41448-95655

Approval date

2010-05-22, 1389/03/01

Ethics committee reference number

1023

Health conditions studied

1

Description of health condition studied

Benign Prostatic Hyperplasia

ICD-10 code

N40

ICD-10 code description

Hyperplasia of prostate

Primary outcomes

1

Description

International score of prostatic signs & symptoms

Timepoint

before intervention and 3 months after that

Method of measurement

IPSS: International Prostatic Symptom Score

Secondary outcomes

1

Description

maximum urinary flow

Timepoint

before intervention and 3 months after that

Method of measurement

uroflometry

2

Description

prostate volume

Timepoint

before intervention and 3 months after that

Method of measurement

sonography

Intervention groups

1

Description

Transurethral injection of Botulinum in prostate

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Ali Hamidi Madani

Street address

Razi Hospital, Sardar Jangal street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasoul Sobhani

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Grant name**Grant code / Reference number**

10506

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Urology Research Center

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

