Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of urodynamic results of Minimistic intra-detrusor Botulinum injection and traditional technique during bladder storage phase in patients with idiopathic over active bladder

Protocol summary

Study aim

Comparison of urodynamic results of Minimistic intra-detrusor botulinum injection and traditional technique during bladder storage phase in patients with idiopathic over active bladder

Design

Two arm parallel group randomized trial with blinded participants, postoperative care and outcome assessment of 78 patients. Randomization was centralized with balance block randomization using excel software.

Settings and conduct

Patients will be visited by urology residents in Tehran Hasheminezhad kidney center hospital and will be entered into trial according to inclusion and exclusion criteria All observers and analyzers are blind about type of interventions .

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Females more than 18 years old with idiopathic over active bladder with no response to medical therapy or contraindicated ones or the ones who suffering from side effects -Exclusion criteria : Males , females under 18 y/o, overactive bladders due to neurogenic disease

Intervention groups

-In traditional method (control group) after general or spinal anesthesia , 0.5 cc Botulinum toxin which has been diluted with 10 cc normal saline is injected into detrusor at 20 sites of bladder (base , laterals and posterior). -In Minimistic method the same diluted Botulinum is injected in 5-6 main sites (base , laterals and posterior) of bladder under local anesthesia. For local anesthesia 100cc Lidocaine 2% is injected in bladder, 15-20 minutes prior to procedure.

Main outcome variables

Comparison of urodynamic results of Minimistic intra-detrusor botulinum injection and traditional technique during bladder storage phase in patients with idiopathic over active bladder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210214050354N1**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **retrospective**

Last update: **2022-06-26, 1401/04/05**
Update count: **0**

Registration date

2022-06-26, 1401/04/05

Registrant information

Name

Niloofar soleimanifard

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4462 0947

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

2021-02-19, 1399/12/01

Actual recruitment end date

2022-03-19, 1400/12/28

Trial completion date

2022-05-05, 1401/02/15

Scientific title

Comparison of urodynamic results of Minimistic intra-detrusor Botulinum injection and traditional technique during bladder storage phase in patients with idiopathic over active bladder

Public title

Comparison of the efficacy of traditional method and modified technique for Botulinum injection in overactive bladder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic overactive bladders resistant to anticholinergic drugs taking at least four weeks. Anticholinergic medication intolerance due to side effects Anticholinergic contraindications

Exclusion criteria:

Neurogenic bladder due to CVA , Multiple sclerosis, Spinal cord injury , head trauma , Parkinson , disc herniations . Severe bladder outlet obstruction Recurrent UTI Urinary tract anomalies Previous bladder surgery History of pelvic radiation History of pelvic malignancies Pregnancy Age < 18 years old Male

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Balance block randomization method : -In the present study we used Block randomization that is a commonly used technique in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms, especially when the sample size is small. The basic idea of block randomization is to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B. then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used. -We consist a 3 columns table in Excel . First one is patients' numbers in order to enter the study . Second one is for their randomized group of intervention (A or B) and the last one is for the codes we will give to patients to make them and the analyzers blind about types of interventions .

Blinding (investigator's opinion)

Triple blinded

Blinding description

1)Patients 2)Observers who evaluate patients 4-6 weeks after procedures by urodynamic 3) Methodologist who analyzes the final data

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of medical science

Street address

Hasheminezhad kidney center Hospital , Valinezhad street , Valiasr BLVD, Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۶۹۷۱۴۷۱۳

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.IUMS.FMD.REC.1399.667

Health conditions studied

1

Description of health condition studied

Idiopathic overactive bladder

ICD-10 code

N00-N99

ICD-10 code description

disease of the genitourinary system

Primary outcomes

1

Description

Comparison of urodynamic results of Minimistic intra-detrusor botulinum injection and traditional technique during bladder storage phase in patients with idiopathic over active bladder

Timepoint

Urodynamic study before Botulinum injection and after 4-6 weeks post injection.

Method of measurement

Urodynamic study

Secondary outcomes

1

Description
Assessing the mean of maximum detrusor pressure in filling phase in traditional method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

2

Description
Assessing the mean of maximum detrusor pressure in filling phase in Minimistic method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

3

Description
Comparison of the mean of maximum detrusor pressure in filling phase in both Minimistic and traditional methods
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

4

Description
Assessing the mean of each detrusor over-activity duration in traditional method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

5

Description
Assessing the mean of each detrusor over-activity duration in Minimistic method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

6

Description
Comparison of the mean of each detrusor over-activity duration in both Minimistic and traditional methods
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

7

Description
Assessing the mean of bladder capacity in beginning of each detrusor over-activity in traditional method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

8

Description
Assessing the mean of bladder capacity in beginning of each detrusor over-activity in Minimistic method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

9

Description
Comparison of the mean of bladder capacity in beginning of each detrusor over-activity in both traditional and Minimistic methods
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

10

Description
Assessing the mean of functional bladder capacity in traditional method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

11

Description
Assessing the mean of functional bladder capacity in Minimistic method
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

12

Description
Comparison of the mean of functional bladder capacity in both traditional and Minimistic methods
Timepoint
Before intervention and 4-6 weeks after Botox injection
Method of measurement
Urodynamic study

13

Description

Assessing the mean of maximum bladder capacity in traditional method

Timepoint

Before intervention and 4-6 weeks after Botox injection

Method of measurement

Urodynamic study

14

Description

Assessing the mean of maximum bladder capacity in Minimistic method

Timepoint

Before intervention and 4-6 weeks after Botox injection

Method of measurement

Urodynamic study

15

Description

Comparison of the mean of maximum bladder capacity in both traditional and Minimistic methods

Timepoint

Before intervention and 4-6 weeks after Botox injection

Method of measurement

Urodynamic study

Intervention groups

1

Description

Control group: As traditional method , spinal or general anesthesia is used. Patients will be hospitalized at least for one day after procedure . In each injection, 0.5 cc Botox are applied by injection at 20 sites of bladder detrusor muscle, mostly in posterior and lateral walls, using Cystoscope . A 500 IU Dysport vial is diluted in 10 cc normal saline for injections.

Category

Treatment - Surgery

2

Description

Intervention group: in Minimistic or the modified method , an oral or IV sedative will be used before procedure. Then 100 cc Lidocaine 2% will be injected in bladder using a 14F Foley catheter. After 15-20 minutes a diluted 500 IU Dysport will be injected at 5-6 main sites, mostly in posterior and lateral walls of bladder, using Cystoscope.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad kidney center

Full name of responsible person

Maryam Emami

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Hasheminejad kidney center , Valinezhad St, Vanak Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person
Maryam Emami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data including age , sex and all urodynamic study results can be shared after eliminating private information of the patients.
When the data will become available and for how long
September 2022
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
1)For research only 2)A researcher or an organization who aim to use the results of the present study must precisely refer to this RCT in details.
From where data/document is obtainable
Email address : n.soleimanifard@gmail.com
What processes are involved for a request to access data/document
1)Evaluating the qualification of the applicants 2)Ensuring that the precise title and information of the current study will be mentioned in their studies. 3)After publishing the results as an article, all researchers can benefit from the published manuscript. We also will provide the pdf of the article should a researcher ask at later stages.
Comments