Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Overactive bladder(OAB) treatment by Intravaginal injection of botulinum toxin A (Dysport): An effective outpatient procedure

Protocol summary

Study aim
Evaluation of the effect of intravaginal injection of Dysport on reducing the symptoms of overactive bladder, as a less invasive method compared to the conventional intravesical injection evaluation the effect of intravaginal injection on reducing pain in patients with overactive bladder suffering from simultaneous chronic pelvic pain syndrome

Design
Two arm parallel groups clinical trial on 50 patients

Settings and conduct
Adult women with overactive bladder who referred to the urology clinic of Labbafinejad Hospital. First group: after receiving regional or general anesthesia, the appropriate dose of Dysport (10 U/kg) is diluted by normal saline (1 cc/100 units). The solution is injected into the detrusor at 20 different points with a special 22 gauge needle through cystoscope, and the Foley catheter is fixed. Second group: local anesthesia is applied on an outpatient basis by lidocaine ,then the standard dose of Dysport is injected in 10 different points of anterior vaginal wall adjacent to the bladder with the fine 31 gauge needle. Foley catheter is not necessary. For all patients, the ICIQ-OAB questionnaire will be completed before and 4 weeks after the intervention. In patients with OAB and CPPS, the VAS-Score questionnaire is completed at the same time intervals.

Participants/Inclusion and exclusion criteria
Inclusion: Adult women with overactive bladder who are candidates for botulinum toxin injection. Exclusion: Under 18 years old, Known cases of neurological defects, Active UTI, Intact hymen

Intervention groups
Control group: receiving Dysport by the standard intravesical method Intervention group: receiving Dysport by the new method of intravaginal injection

Main outcome variables
The rate of OAB symptoms reduction The rate of pain reduction Complications Rate: Hematuria, dysuria, infection, need for intermittent catheterization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211203053261N1**
Registration date: **2022-05-28, 1401/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-28, 1401/03/07**
Update count: **0**

Registration date
2022-05-28, 1401/03/07

Registrant information

Name
Maede Mohseni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Overactive bladder(OAB) treatment by Intravaginal injection of botulinum toxin A (Dysport): An effective outpatient procedure

Public title
Overactive bladder treatment by Intravaginal injection of botulinum toxin A
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult women with overactive bladder who have not responded to initial medical treatment
Exclusion criteria:
Age under 18 years patients with neurogenic bladder (known cases of neurological defects) Active UTI Women with intact Hymen
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of urology and nephrology research center, Shahid Beheshti university of medical sc
Street address
No 103, Boostan 9, Pasdaran AV, Tehran
City
Tehran
Province
Tehran
Postal code
16666663111

Approval date
2021-10-02, 1400/07/10
Ethics committee reference number
IR.SBMU.UNRC.REC.1400.005

Health conditions studied

1

Description of health condition studied
overactive bladder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
ICIQ-OAB symptom score
Timepoint
Before and 4 weeks after intervention
Method of measurement
Validated questionnaire

Secondary outcomes

1

Description
Pain severity
Timepoint
Before and 4 weeks after intervention
Method of measurement
VAS score

2

Description
Incidence of gross hematuria
Timepoint
Within a week after the intervention
Method of measurement
View Foley catheter / Ask the patient

3

Description
Incidence of dysuria
Timepoint
Within a week after the intervention
Method of measurement
Ask the patient

4

Description
Incidence of UTI
Timepoint
Within a week after the intervention
Method of measurement
Urine culture

5

Description
Incidence of urinary retention and need for CIC
Timepoint
Within a week after the intervention
Method of measurement
Ultrasonography and ask the patient

Intervention groups

1

Description
Intervention group: Intravaginal Dysport (Abobotulinum toxin A, Ipsen Biop- harmaceuticals, Pharma, Germany) injection: In this group, local anesthesia is applied on an outpatient basis; diluted lidocaine is injected in to the anterior wall of the vagina at the lithotomy position. The standard dose of Dysport (10 units per kilogram of patient's body weight) is then diluted by injectable normal saline (1 cc per 100 units) and injected into 10 points of the anterior vaginal wall, adjacent to the bladder, by an insulin syringe (very fine 31 gauge needle). Foley catheter is not necessary at the end of procedure.
Category
Treatment - Surgery

2

Description
Control group: Intravesical Dysport (Abobotulinum toxin A, Ipsen Biop- harmaceuticals, Pharma, Germany) injection: After regional or general anesthesia, cystoscopy and bladder washing are performed at the lithotomy position . The appropriate dose of Dysport, equivalent to 10 units per kilogram of patient weight (maximum 1000 units), is diluted with injectable normal saline (1 cc per 100 units). The final solution is injected into 20 different points of detrusor muscle by a special 22 gauge bladder injection needle (BoNee ;Coloplast, Humlebaek, Denmark) through cystoscope, and Foley catheter is fixed at the end of the procedure.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labbafinejad medical center
Full name of responsible person
Farzaneh Sharifiaghdas
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Urology and Nephrology Research Center
Grant code / Reference number
0
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Hamedan University of Medical Sciences
Full name of responsible person
Maede Mohseni
Position
Assistant professor

Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The information will be entered as code in SPSS software and the analysis results will be published as a final report and article
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
According to the proposal, the data will be entered in accordance with the variables in SPSS software
When the data will become available and for how long
All information will be provided to the Research Center after the approval of the final report and preparation of the article
To whom data/document is available
Executors of the project
Under which criteria data/document could be used
If you need to continue the project with a larger sample size after preparing the proposal and approving it
From where data/document is obtainable
Urology and nephrology research center
What processes are involved for a request to access data/document
After the approval of the executor of the project and approval in the research council of the research center
Comments