Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the clinical consequences of botulonium toxin a compared to medical treatment in patients with urge incontinence

Protocol summary

Study aim
Evaluation of the clinical consequences of botulonium toxin a compared to medical treatment in patients with urge incontinence

Design
Clinical trial without a control group, three parallel groups, double-blind, randomized with 60 patients. Randomized using www.randomization.com website.

Settings and conduct
Urge incontinence patients refer to Imam Khomeini Hospital in Tehran. Participants are randomly assigned to three groups. Also, participants and assessors of the outcome will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Accurate diagnosis of patients with urge incontinence based on the diagnosis of a pelvic floor specialist, women over the age of 18, suffering from urge incontinence and in the case of a history of non-response to antimuscarinic drugs in the past 3 months; Urgent incontinence and having a history of antimuscarinic drug complications (constipation, blurred vision, dry mouth) Patients with urinary tract infection, interstitial cystitis, having an intermittent or permanent catheter and previous pelvic radiotherapy treatment and neurogenic urge incontinence and a history of sensitivity to Botox; Use of aminoglycoside drugs and contraindications for receiving antimuscarinic treatment (tachyrhythmia, angle-closure glaucoma)

Intervention groups
One group (20 people) received routine treatment of 200 units of botulinum toxin A in the operating room by the pelvic floor disorders fellowship. The other group (20 people) received routine treatment in the amount of a single injection of 300 Botox units into the bladder muscle (intra detrusor) by the pelvic floor disorders fellowship in the operating room. The third group (20 people) are treated with antimuscarinic drugs (solifenacin 5 mg orally daily for 6 months).

Main outcome variables
Frequency of urination, score of ICIQ-OAB questionnaire, side effects of botox, side effects of solifenacin drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230508058117N1**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**
Update count: **0**

Registration date
2023-11-20, 1402/08/29

Registrant information

Name
Fatemeh Hosseini Salkisari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6119 2363

Email address
hosseini.m.f.11@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-06-19, 1403/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the clinical consequences of botulonium toxin a compared to medical treatment in patients with urge incontinence

Public title
Evaluation of the clinical consequences of botulonium toxin a compared to medical treatment in patients with urge incontinence

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Accurate diagnosis of patients with urge incontinence based on the diagnosis of a pelvic floor specialist, women over the age of 18, suffering from urge incontinence and in the case of a history of non-response to antimuscarinic drugs in the past 3 months; Urgent incontinence and having a history of antimuscarinic drug complications (constipation, blurred vision, dry mouth)

Exclusion criteria:
Patients with urinary tract infection, interstitial cystitis, having an intermittent or permanent catheter previous pelvic radiotherapy treatment neurogenic urge incontinence a history of sensitivity to Botox; Use of aminoglycoside drugs contraindications for receiving antimuscarinic treatment (tachyrhythmia, angle-closure glaucoma)

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, all eligible patients were assigned to three groups using random sequence extraction from the computer (via www.randomization.com) and simple randomization. The resulting random numbers, i.e. the allocation of patients to groups, was concealed using sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither the patients nor the researcher know the type of intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of tehran University of Medical Sciences

Street address
Tehran, District 6, Pour Sina St

City
Tehran

Province
Tehran

Postal code
1461884513

Approval date
2023-06-20, 1402/03/30

Ethics committee reference number
IR.TUMS.IKHC.REC.1402.255

Health conditions studied

1

Description of health condition studied
urge incontinence

ICD-10 code
N39.41

ICD-10 code description
Urge incontinence

Primary outcomes

1

Description
ICIQ-OAB questionnaire score

Timepoint
Before treatment, one week, 1 month after treatment

Method of measurement
Patient's answer

Secondary outcomes

empty

Intervention groups

1

Description
The first group: receive routine treatment of 200 units of botulinum toxin.

Category
Treatment - Drugs

2

Description
Group 2: They receive routine treatment with a single injection of 300 units of Botox into the bladder muscle (intra detrusor).
Category
Treatment - Drugs

3

Description
Group 3: treated with antimuscarinic drugs (solifenacin 5 mg orally daily for 6 months)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Fatemeh Hosseini Selaki Seri
Street address
At the end of Keshavarz Boulevard, Doctor Gharib Street
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6119 0000
Email
hosseini.m.f.11@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Seyyed Abbas Motavalian
Street address
Tehran, District 6, Pour Sina
City
Tehran
Province
Tehran
Postal code
1461884513
Phone
+98 21 6119 0000
Email
amotevalian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Hosseini Selaki Seri
Position
fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran, District 6, Pour Sina St
City
Tehran
Province
Tehran
Postal code
1461884513
Phone
+98 21 6119 0000
Email
hosseini.m.f.11@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Hosseini Selaki Seri
Position
fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran, District 6, Pour Sina St
City
Tehran

Province
Tehran
Postal code
1461884513
Phone
+98 21 6119 0000
Email
hosseini.m.f.11@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Hosseini Selaki Seri
Position
fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tehran, District 6, Pour Sina St
City
Tehran
Province
Tehran
Postal code
1461884513
Phone
+98 21 6119 0000
Email
hosseini.m.f.11@gmail.com

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 individual data of the participants in this study will be shared after unidentifiable individuals
When the data will become available and for how long
The access period will start from 2022to 2023
To whom data/document is available
Data will be available to researchers working in the university.
Under which criteria data/document could be used
Just for performing research
From where data/document is obtainable
Refer to the responsible person for accessing the data
What processes are involved for a request to access data/document
The data will be available one month after the responsible person's approval
Comments