

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

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

Protocol summary

Study aim

Evaluation of the clinical consequences of botulinum 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 (tachyarrhythmia, 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 botulinum toxin a compared to medical treatment in patients with urge incontinence

Public title

Evaluation of the clinical consequences of botulinum 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 (tachyarrhythmia, 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

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Tehran

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Tehran

Postal code

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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

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Tehran

Province

Tehran

Postal code

1461884513

Phone

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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

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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

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Hosseini Selaki Seri

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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 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