

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Botulinum A toxin versus anticholinergic on clinical symptoms of patients with overactive bladder: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of Botulinum A toxin versus anticholinergic on clinical symptoms of patients with overactive bladder

Design

This is a Phase III randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Beheshti Hospital in Hamadan city, involving 42 eligible patients with overactive bladder. The patients will be randomly assigned to the intervention and control groups through the block randomization. However, it should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 80 years Overactive bladder
Exclusion criteria: Pregnancy or breastfeeding
Neuromuscular diseases Taking anticoagulants Allergy to egg white

Intervention groups

Intervention group: Injection of 100 to 300 units of Botulinum A toxin in 20 to 30 points of the bladder wall with the help of a cystoscope under spinal anesthesia plus one gram of intravenous cephalin antibiotic Control group: Anticholinergic drugs include Urinacin 10 mg daily plus oxybutynin 5 mg every 12 hours for 3 month.

Main outcome variables

Primary outcome: Severity of clinical symptoms (frequency, urgency, nocturia)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N488**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **prospective**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Botulinum A toxin versus anticholinergic on clinical symptoms of patients with overactive bladder: a randomized clinical trial

Public title

Effect of Botulinum A toxin versus anticholinergic on clinical symptoms of patients with overactive bladder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 80 years Overactive bladder

Exclusion criteria:

Pregnancy or breastfeeding Neuromuscular diseases

Taking anticoagulants Allergy to egg white

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-10-28, 1402/08/06

Ethics committee reference number

IR.UMSHA.REC.1402.495

Health conditions studied

1

Description of health condition studied

Overactive bladder

ICD-10 code

N32.81

ICD-10 code description

Overactive bladder

Primary outcomes

1

Description

Severity of clinical symptoms (frequency, urgency, nocturia)

Timepoint

Before the intervention and 3 months later

Method of measurement

Using International Incontinence Consultation Questionnaire (ICIQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 100 to 300 units of Botulinum A toxin in 20 to 30 points of the bladder wall with the help of a cystoscope under spinal anesthesia plus one gram of intravenous cephalin antibiotic

Category

Treatment - Drugs

2

Description

Control group: Anticholinergic drugs include Urinacin 10 mg daily plus oxybutynin 5 mg every 12 hours for 3 month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital in Hamadan city

Full name of responsible person

Narges Ahmadvan

Street address

Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

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

Hamedan 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

Narges Ahmadvand

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available