Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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

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Province

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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Person responsible for updating data

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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