Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The survey effects of botulinum toxin A on quality of life in women with overactive bladder and urge urinary incontinence

Protocol summary

Study aim

The effects of Botulinum Toxin A on quality of life in women with overactive bladder and urge urinary incontinence in patient In Imam Reza Hospital in Kermanshah city

Design

In this research, 50 women with overactive bladder and urge urinary incontinence referring to Imam Reza Teaching Hospital were chosen purposefully. This study is clinical trial without control group.

Settings and conduct

This study as non-blinded will be done in Imam Reza Hospital in Kermanshah. Patients with urge incontinence and overactive bladder who have failed to respond to anticholinergic treatments or had side effects, 150 units of botulinum toxin A will be injected to 20 bladder dentures.Urinary incontinence and quality of life before treatment and one and six months after the treatment will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Aged over 50 years and menopause; Married; Having overactive bladder symptoms three or more during the day; Having urge urinary incontinence; Going to a toilet 8 times or more during the day for 3 days based on the urinary notes. Exclusion Criteria: Diabetes history; Hypertension, neurological diseases such as multiple sclerosis, myasthenia gravis, and stroke; Urinary incontinence prevalence; Major uterine masses and history of chronic urinary tract infections.

Intervention groups

Patients with urge incontinence and overactive bladder who have failed to respond to anticholinergic treatments or had side effects will be injected with 150 units of Botulinum toxin A at the 20 point of detrusor muscle

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100301003461N10**
Registration date: **2018-07-06, 1397/04/15**
Registration timing: **retrospective**

Last update: **2018-07-06, 1397/04/15**
Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

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Firoozeh Veisi
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Kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences

Expected recruitment start date

2017-07-19, 1396/04/28

Expected recruitment end date

2018-01-18, 1396/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The survey effects of botulinum toxin A on quality of life in women with overactive bladder and urge urinary incontinence

Public title
The survey effects of botulinum toxin A on quality of life in women with overactive bladder and urge urinary incontinence in patient in Imam Reza Hospital in Kermanshah in 2017

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Aged over 50 years and Menopause Married Having overactive bladder symptoms Those who have not responded to anticholinergicmedications Have side effects Have a BMI of between 20-30 Anticholinergic drugs should not be used for 7 days prior of examination and during treatment Patients should have a residual urine of 100 cc or Less Mentally and physically capable of intermittent catheterization urge urinary incontinence

Exclusion criteria:
Diabetes history Hypertension history Neurological Diseases such as multiple sclerosis, Myasthenia Gravis and Stroke, Alzheimer's disease, Psychiatric Disorders, Major Uterine Masses History of Chronic Urinary Tract Infections

Age
From **50 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic's committee of Kermanshah University of Medical Sciences

Street address
Kermanshah, Shahid Beheshti Blvd, Building No. 2, Research and Technology Dept

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
IR.KUMS.REC.1396.194

Health conditions studied

1

Description of health condition studied
Overactive bladder syndrome

ICD-10 code
n32.8

ICD-10 code description
other specified disorders of bladder

Primary outcomes

1

Description
quality of life in women with overactive bladder and urge urinary incontinence

Timepoint
Before Treatment, One Months After treatment,Six Months After Treatment

Method of measurement
I-QOL Questionnaire to Measure The Effects of Urge Urinary Incontinence on Quality of Life

2

Description
urinary incontinence

Timepoint
Before Treatment, One Months After treatment,Six Months After Treatment

Method of measurement
Ask the patient

Secondary outcomes

1

Description
Urinary Tract Infection

Timepoint
Before treatment, one months after treatment,six months after treatment

Method of measurement
Experiment results

2

Description
Hematuria
Timepoint
Before treatment, one month after treatment, six months after treatment
Method of measurement
Observation and experiment results

3

Description
Dysuria
Timepoint
Before treatment, one month after treatment, six months after treatment
Method of measurement
Ask the Patient

Intervention groups

1

Description
The patient in the operating room will be undergoing cystoscopy by a urologist and assistant women's participation, and toxin botulinum A at 0.5 ccs will be injected with a needle in 20 points of the bladder muscle. (About 150 units) The injection will not be done in the trigone area.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Teaching Hospital
Full name of responsible person
Dr.Masoumeh Bayati
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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
Kermanshah 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
Kermanshah university of Medical Sciences
Full name of responsible person
Dr. Masoumeh Bayati
Position
Resident of Gynecology and Obstetrics
Latest degree
Medical doctor
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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