

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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

Name

Firoozeh Veisi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1823 4276

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f_veisi@kums.ac.ir

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 anticholinergic medications 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

Street address

Nursing Blvd, Imam Reza Teaching Hospital
,Kermanshah, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Farid Najafi

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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

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Firoozeh Veisi

Position

Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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