Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effectiveness of botulinum A subdermal injection in the treatment of patients with premature ejaculation resistant to treatment: a clinical trial

Protocol summary

Study aim

Effectiveness of intradermal botulinum a injection in the treatment of treatment-resistant premature ejaculation patients

Design

Clinical trial with two patient groups, parallel, treatment, balanced block randomization, single-blind (researcher). 30 patients referred to Sinai Hospital.

Settings and conduct

This clinical trial will be conducted in Tehran Sina Hospital, Urology Research Center, single-blind (researcher), balanced block randomization and Weber on 30 patients. Patients are divided into two groups: First group: injection of 100 units of botulinum toxin-A with a concentration of 100 units/ml under the skin of the glans region: 15 patients. The second group: injection of 1 cc of normal saline under the skin of the glans region: 15 patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent of the patients / having premature ejaculation resistant to treatment. Exclusion criteria: other sexual diseases such as impotence and decreased sexual desire / any skin disease and infection of the genital area / history of allergy to injectable drugs / injecting drug addicts or any drug addiction/patients who are withdrawing from drugs

Intervention groups

The first group: injection of 100 units of botulinum toxin-A with a concentration of 100 units/ml under the skin of the glans region: 15 patients The second group: injection of 1 cc of normal saline under the skin of the glans region: 15 patients

Main outcome variables

Intravaginal ejaculation delay time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N23**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **prospective**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date

2023-12-07, 1402/09/16

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-16, 1402/12/26

Expected recruitment end date

2025-03-16, 1403/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effectiveness of botulinum A subdermal injection in the treatment of patients with premature ejaculation resistant to treatment: a clinical trial

Public title
The effectiveness of botulinum A injection in the treatment of premature ejaculation patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent from patients Having treatment-resistant premature ejaculation

Exclusion criteria:
Other sexual diseases such as erectile dysfunction and decreased libido Any skin disease and genital infection History of allergy to injectable drugs Injection drug addicts or any type of drug addiction Patients who are withdrawing from drugs

Age
No age limit

Gender
Male

Phase
3

Groups that have been masked

- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the Permuted balanced block randomization method will be used by creating blocks of four between the two treatment and control groups in a random way. According to the randomization method, the two groups will have a difference of at most two people in the number of allocated people. After the statistics and epidemiology specialist prepares the randomization sequence, the patients will be placed in blocks a and b. Based on the first selection of the patient as a (first group), the next patient will be placed in group b (second group).

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be single-blind. The researcher will not know about the treatment process. The researcher will not know about injecting 100 units of botulinum toxin-A with a concentration of 100 units/ml or injecting one cc of normal saline under the skin of the glans.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee, Sina Hospital

Street address
Room 206, Ethics Committee Office، Second Floor, Administrative Building،Sina Hospital، Imam Khomeini Street,Tehran,Iran

City
Tehran

Province
Tehran

Postal code
1136746911

Approval date
2023-10-22, 1402/07/30

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1402.090

Health conditions studied

1

Description of health condition studied
Premature ejaculation in patients

ICD-10 code
F52.4

ICD-10 code description
Premature ejaculation

Primary outcomes

1

Description
Intravaginal ejaculation latency

Timepoint
Before and 4 weeks after injection

Method of measurement
Premature ejaculation diagnosis questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 100 units of botulinum toxin-A with a concentration of 100 units/ml under the skin of the glans region: 15 patients

Category
Treatment - Drugs

2

Description

Control group: Injection of 1 cc of normal saline under the skin of the glans region: 15 patients

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

Street address

Urology Research Center, Sina Hospital, Imam Khomeini St., Tehran, Iran .

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.

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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

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

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Mohammad Kazem Aghamir

Position

Head of Urology Research Center

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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Researcher

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Ph.D.

Other areas of specialty/work
Medical Biology

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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
No - There is not a plan to make this available

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

Title and more details about the data/document
Demographic information anonymously

When the data will become available and for how long
One year after publication

To whom data/document is available
Researchers working in academia, physicians, surgeons and hospitals.

Under which criteria data/document could be used
Any analysis can be done with the consent of the main researcher

From where data/document is obtainable
Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560 mkaghamir@tums.ac.ir

What processes are involved for a request to access data/document
After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by providing a patient's privacy.

Comments