

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 .

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Fax

+98 21 6634 8553

Email

mkaghamir@tums.ac.ir

Web page address

<http://urc.tums.ac.ir>

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.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

<http://vcr.tums.ac.ir/>

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

Street address

Urology Research Center- Sina Hospital - Imam Khomeini St

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8560

Fax

+98 21 6634 8561

Email

mirzaee.scholar@gmail.com

Web page address

<https://URC@tums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Kazem Aghamir

Position

Head of Urology Research Center

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Urology Research Center- Sina Hospital - Imam

Khomeini St
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
+98 21 6634 8561
Email
mkaghamir@tums.ac.ir
Web page address
<http://urc.tums.ac.ir>

Person responsible for updating data

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
Street address
Urology Research Center- Sina Hospital - Imam
Khomeini St
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
+98 21 6634 8561

Email
mirzaee.scholar@gmail.com
Web page address
<https://URC@tums.ac.ir>

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