

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Efficacy of Intracavernosal Injections of 50 units versus 100 units Abo botulinum toxinA (Dysport®) in vasculogenic Erectile Dysfunction with Phosphodiesterase Type 5 Inhibitors resistant

Protocol summary

Study aim

Efficacy of Intracavernosal Injections of 50 units versus 100 units Abo botulinum toxinA (Dysport®) in vasculogenic Erectile Dysfunction with Phosphodiesterase Type 5 Inhibitors resistant

Design

Clinical trial without control group with two parallel group, blinded outcomes assessment, with simple randomization, design for 20 patients, phase 2-3.

Settings and conduct

In this study, out patients who refer to Imam Khomeini hospital in Ahvaz that were qualified for this study got comforted with IIEF, SHIM score, Erection hardness score and Doppler Sonography with Papaverine injection. Then patients were divided into two groups. One group was treated with a single dose of 50 units Dysport and the other group was treated with a single dose of 100 units. Only the person who injected the drug knows the dosage of Dysport while sonographer, person who have collected the data and patients don't know about the dosage.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 to 70 years of age, erectile dysfunction confirmed with colour Doppler sonography and failure to response to first line treatments. exclusion criteria: cardiovascular diseases that interfere with erectile function,unstable physical and psychological situations,anatomical abnormality of penis,hormonal disorder and history of spinal cord surgery or radical pelvic surgery.

Intervention groups

Patients with 5 phosphodiesterase inhibitor resistant Vasculogenic erectile dysfunction (arterial insufficiency) confirmed by Doppler Sonography with Papaverine injection

Main outcome variables

In this study, we evaluate the success rate of this

method in patient with first lines resistant erectile dysfunction and based on the results of this study we can use new and safe line for these patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201119049439N1**

Registration date: **2020-12-10, 1399/09/20**

Registration timing: **prospective**

Last update: **2020-12-10, 1399/09/20**

Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

sajad moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3292 3985

Email address

sajadsamyar1365@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

2020-12-21, 1399/10/01

Actual recruitment end date

2021-04-21, 1400/02/01

Trial completion date

2021-04-21, 1400/02/01

Scientific title

Efficacy of Intracavernosal Injections of 50 units versus 100 units Abo botulinum toxinA (Dysport®) in vasculogenic Erectile Dysfunction with Phosphodiesterase Type 5 Inhibitors resistant

Public title

Efficacy of Dysport on erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

40 to 70 years of age Erectile Dysfunction proved by colour doppler sonography Failure to response to first lines treatments

Exclusion criteria:

significant cardiovascular diseases that interfere with erectile function History of unstable physical and psychological situations Anatomical abnormalities of the penis Hormonal disorders History of spinal cord or pelvic radical surgery

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study randomization performed with simple randomization, personal, with statistical software usage.

Blinding (investigator's opinion)

Double blinded

Blinding description

Only drug injector knows the drug dosage. Sonographer, the person who collects the data and the patient don't know the dosage.

Placebo

Not used

Assignment

Parallel

Other design features

Patients in two groups received the same intervention (drug injection) but with two different dosages.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan center of Ahvaz university of medical sciences

Street address

Imam Khomeini hospital, Azadegan street

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Approval date

2020-11-17, 1399/08/27

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.105

Health conditions studied**1****Description of health condition studied**

Erectile dysfunction

ICD-10 code

N52.9

ICD-10 code description

Male erectile dysfunction, unspecified

Primary outcomes**1****Description**

peak systolic velocity in cavernosal artery

Timepoint

Before and after Intracavernosal injection of 50 and 100 units Dysport

Method of measurement

Sonography

2**Description**

end diastolic velocity in cavernosal artery

Timepoint

Before and after Intracavernosal injection of 50 and 100 units Dysport

Method of measurement

Sonography

3**Description**

International Index of Erectile Function(IIEF)

Timepoint

Before and after Intracavernosal injection of 50 and 100 units Dysport

Method of measurement

Questionnaire

4**Description**

Sexual Health Inventory for Men(SHIM SCORE)

Timepoint

Before and after Intracavernosal injection of 50 and 100 units Dysport

Method of measurement

Questionnaire

5**Description**

Erection Hardness Score

Timepoint

Before and after Intracavernosal injection of 50 and 100 units Dysport

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group1: qualified patients that have vasculogenic erectile dysfunction confirmed by Doppler sonography will be affected with 50 units intracavernosal Dysport injection.

Category

Treatment - Drugs

2**Description**

Intervention Group2: qualified patients that have vasculogenic erectile dysfunction confirmed by Doppler sonography will be affected with 100 units intracavernosal Dysport injection.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital in Ahvaz

Full name of responsible person

Dinyar Khazaeli

Street address

Azadegan street, Imam khomeini hospital

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6193673111

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+98 61 3222 2818

Email

himam@ajums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dinyar Khazaeli

Street address

Ahvaz university of medical science in Golestan

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Province

Khouzestan

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6135715794

Phone

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Email

fmedicine@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Sajad Moradi

Position

Resident of urology

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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No. 68, second Left street, Phase 3 street, Melat alley.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dinyar khazaeli

Position

Urologist

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Sajad Moradi

Position

Resident of urology

Latest degree

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after anonymising the patients.

When the data will become available and for how long

Access period will start after publishing the results.

To whom data/document is available

Everybody

Under which criteria data/document could be used

There is no barrier to access.

From where data/document is obtainable

Azadegan street, Imam Khomeini hospital . email: sajadsamyar1365@gmail.com. postal code:6193673111

What processes are involved for a request to access data/document

After requesting using email

Comments