

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of patients' satisfaction with the effectiveness of dapoxetine in premature ejaculation and its complications

Protocol summary

Study aim

Determining and Comparing the Satisfaction and Effectiveness of Dapoxetine in Patients Before and After Dapoxetine administration

Design

Patients with premature ejaculation referred to the office in a semi-experimental manner in 2019 to 2020 with a sample number of 100 people.

Settings and conduct

This study was performed on patients with premature ejaculation who referred to the office of the urology professors of the faculty of the Islamic Azad University, Shahroudeh Branch. The semi-experimental form (before and after taking the drug) will be performed in 2019 to 2020

Participants/Inclusion and exclusion criteria

People with the following conditions will enter the study:

1. Have ejaculatory ejaculation
2. Be at least 20 to 40 years old
3. Tendency to take medications regularly and continuously until the end of the treatment period
4. Have a desire to participate and cooperate in this research
5. Have at least once a week close and in case of the following conditions, they will be excluded from the study:

1. Do not have any contraindications to the use of drugs
2. Have no history of drug and alcohol use continuously
3. Disorder of erection, genital urinary tract infection, systemic or neurological disorder, do not have severe mental disorder
4. Do not have a history of IHD, DM, HTN, HLP and severe vascular disorders as proven

Intervention groups

Patients studied for 30 mg dapoxetine tablets are given two hours before intercourse, one-month treatment period and are asked to complete the questionnaires

Main outcome variables

Premature ejaculation time; satisfaction with treatment; side effects of treatment; effectiveness of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200624047912N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Saeed Tavakoli nezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 0745

Email address

Saeedtin.tavakolii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-07-15, 1399/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of patients' satisfaction with the effectiveness of dopoxetin in premature ejaculation and its complications		Central Building, Islamic Azad University, next to the gas station	
Public title	Evaluation of patients' satisfaction with the effectiveness of dopoxetin in premature ejaculation and its complications	City	Shahrood
Purpose	Treatment	Province	Semnan
Inclusion/Exclusion criteria		Postal code	4318936199
Inclusion criteria:	Have ejaculatory ejaculation Be at least 20 to 40 years old Tendency to take medications regularly and continuously until the end of the treatment period Have a desire to participate and cooperate in this research 5. Have at least once a week close	Approval date	2019-03-09, 1397/12/18
Exclusion criteria:	Do not have any contraindications to the use of drugs (sensitivity to SSRI_ alcohol consumption_ calculation of lactose_ history of heart problem_depression) You have become _strength of safety_consumption of tramadol_ _MAOI Have no history of drug and alcohol use continuously Disorder of erection, genital urinary tract infection, systemic or neurological disorder, do not have severe mental disorder Do not have a history of IHD, DM, HTN, HLP and severe vascular disorders as proven	Ethics committee reference number	IR.IAU.SHAHROOD.REC.1397.044
Age	From 20 years old to 40 years old	Health conditions studied	
Gender	Male	1	
Phase	2	Description of health condition studied	
Groups that have been masked	No information	Premature ejaculation	
Sample size	Target sample size: 100	ICD-10 code	
Randomization (investigator's opinion)	N/A	F52.4	
Randomization description		ICD-10 code description	
Blinding (investigator's opinion)	Not blinded	Premature ejaculation	
Blinding description		Primary outcomes	
Placebo	Not used	1	
Assignment	Single	Description	
Other design features		Ejaculation time	
Secondary Ids		Timepoint	
empty		Before treatment - 10 days after treatment - one month later	
Ethics committees		Method of measurement	
1		Questionnaires 1, 2 and 3whith Using a timer to minute	
Ethics committee		2	
Name of ethics committee		Description	
Ethics committee of Islamic Azad University Shahrood		Drug side effects	
Branch		Timepoint	
Street address		10 days after treatment - one month later	
		Method of measurement	
		Questionnaires 2 and 3 mention the specified options	
		3	
		Description	
		Satisfaction with treatment	
		Timepoint	
		10 days after treatment - one month later	
		Method of measurement	
		Questionnaires 2 and 3 mention excellent, good, medium, poor	
		Secondary outcomes	
		1	
		Description	
		Ejaculation time score	
		Timepoint	

Before treatment - 10 days after treatment - one month later

Method of measurement

Questionnaires 1, 2 and 3 with the option marked to the time score

Intervention groups

1

Description

This study will be performed on patients with premature ejaculation in a semi-experimental manner. Dapoxetine 30 mg oral tablets are given by Kosar Pharmaceutical Company and Complete the questionnaires 10 days later and one month before treatment. Dapoxitin pharmacology is a selective inhibitor of short-term serotonin reuptake inhibitors.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam alania hospital

Full name of responsible person

Seyed Vahid Sadr Bolorian

Street address

Khatam Alanbia Hospital, Daneshgah blvd.

City

Shahrood

Province

Semnan

Postal code

3614871151

Phone

+98 23 3239 2661

Fax

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Email

khatam-shahrood.ac@email.com

Web page address

<http://khatam.iau-shahrood.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Behroz Yahyaei

Street address

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Email

khatam-shahrood.ac@email.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Seyed Vahid Sadr Bolorian

Position

PHD

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Seyed Vahid Sadr Bolorian

Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Saeed Tavakoli Nezhad
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intern
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A Level or less
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General Practitioner
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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
No - There is not 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
Not applicable