

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comprative Study of Therapeutic Effects of Sertraline, Flouxetine, Paroxetine and Citalopram in Premature Ejaculation

Protocol summary

Study aim

Comprative study of therapeutic effect and Complication of Drugs of Sertraline, Flouxetine, Paroxetine and Citalopram each 12 hours Daily in Premature Ejaculation Patients

Design

This study is a randomized, non-placebo-controlled clinical trial and a comparative study on the therapeutic effect of sertraline, Flouxetine, Paroxetine and Citalopram every 12 hours daily in the treatment of premature ejaculation patients. Four hundred eighty patients (each group of one hundred twenty) will be surveyed from July 2018 to July 2020.

Settings and conduct

The location of the study is in the Imam Reza hospital of Tehran affiliated to the Army University of Medical Science. Patients are evaluated by an urologist and, if approved, have an early ejaculation according to the definition of DMS-4 enrolled In this study, after obtaining consent Written.

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Male with Premature Ejaculation: Possible at least Once Coitus on Week and Age between 20 to 75 years Exclusion Criteria : Norologic Disorder: Psychologic Disorder: Age Less than 20 and Over 75 Years: Urinary and Genital Infection and History of Pelvic Surgery

Intervention groups

In the first group, it is prescribed 50 mg of sertraline, in the second group 20 mg flouxetine, in the third group 20 mg paroxetine and in the fourth group 20 mg citalopram each 12 hours daily . Finally, the time the ejaculation before treatment (mean time in at least three coitus) and at the end of the fourth and eighth weeks after treatment are accurately measured and recorded by the patient's wife with a stopwatch . Patients are advised to record time from vaginal entrance to ejaculation

Main outcome variables

Time of Ejaculation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180401039167N2**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**

Update count: **1**

Registration date

2018-06-25, 1397/04/04

Registrant information

Name

Bijan Rezakhaniha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 6431

Email address

reza.bijan1345@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of Therapeutic Effects of Sertraline, Fluoxetine, Paroxetine and Citalopram in Premature Ejaculation

Public title

Study of Therapeutic Effects of Sertraline, Fluoxetine, Paroxetine and Citalopram in Premature Ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male with Premature Ejaculation Possible at least Once Coitus a Week Age between 20 to 75 years

Exclusion criteria:

Norologic Disorder Age Less than 20 and Over 75 Years
Psychologic Disorder History of Pelvic Surgery Urinary and Genital Infection

Age

From **20 years** old to **75 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **480**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method in this research is Simple Randomization. Randomization unit was individual and patients randomization method is computerized random numbers. The starting point is completely random (selecting a number on the table with closed eyes) and the direction of movement in the table is selected to the bottom. The patients are randomly assigned to one of the study groups using the random numbers table and receive the relevant intervention.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Army University of Medical

Sciences

Street address

Emam Reza Hospital, Sarhang Etemadzadeh Ave, Fatemi Ave

City

Tehran

Province

Tehran

Postal code

IR.26.110791

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.AJAUMS.REC.1396.112

Health conditions studied

1

Description of health condition studied

Premature Ejaculation

ICD-10 code

F52.4

ICD-10 code description

Premature ejaculation

Primary outcomes

1

Description

Time of Ejaculation (From Vaginal Entrance to Ejaculation)

Timepoint

The Time of Ejaculation at the Beginning of the Study (Before the Intervention) and 4 and 8 weeks after the start of Drug

Method of measurement

Measure the time in seconds by the stopwatch by the patient's wife

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sertraline will receive 50 mg every 12 hours from Abidi-Tehran Pharmaceutical Company for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Fluoxetine will receive 20 mg every 12 hours from Abidi-Tehran Pharmaceutical Company for 8 weeks.

Category

Treatment - Drugs

3**Description**

Intervention group: Paroxetine will receive 20 mg every 12 hours from Abidi-Tehran Pharmaceutical Company for 8 weeks.

Category

Treatment - Drugs

4**Description**

Intervention group: Citalopram will receive 20 mg every 12 hours from Abidi-Tehran Pharmaceutical Company for 8 weeks.

Category

Treatment - Drugs

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

Emam Reza hospital

Full name of responsible person

Bijan Rezakhaniha

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Emam Reza hospital, Sarhang Etemadzadeh Ave, Fatemi St

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reza.bijan@yahoo.com

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

Artesh University of Medical Sciences

Full name of responsible person

Dr Arsia Taghva

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Aja University of Medical Sciences, Sarhang Etemadzadeh Ave, Fatemi S

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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

Artesh 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**

Artesh University of Medical Sciences

Full name of responsible person

Bijan Rezakhaniha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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

Artesh University of Medical Sciences

Full name of responsible person

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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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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