

# 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

**Street address**

Emam Reza hospital, Sarhang Etemadzadeh Ave,  
Fatemi St

**City**

Tehran

**Province**

Tehran

**Postal code**

IR.26.110791

**Phone**

+98 21 8609 5072

**Email**

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

**Street address**

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

**City**

Tehran

**Province**

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**Phone**

+98 21 8609 5232

**Email**

reza.bijan1345@gmail.com

**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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**Email**

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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