

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparative Study of Therapeutic Effect of Two Medicinal Procedures of Sertraline in Premature Ejaculation

#### Protocol summary

##### Study aim

Comparative study of therapeutic effect of two medicinal procedures of Sertraline 4 hours before coitus and each 12 hours in premature ejaculation, and declining symptoms of drug in patients through decreasing dosage and therapeutic procedure in patients

##### Design

This study is a randomized, non-placebo-controlled clinical trial and a comparative study on the therapeutic effect of sertraline therapy every 12 hours and 4 hours before coitus in the treatment of premature ejaculation and dose reduction and therapeutic treatment in patients. One hundred twenty patients (each group of sixty) will be surveyed from July 2017 to July 2018.

##### 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 a 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 65 years. Exclusion Criteria: Neurologic Disorder; Psychologic Disorder; Age Less than 20 and Over 65 Years; Urinary and Genital Infection and History of Pelvic Surgery

##### Intervention groups

In the first group, it is prescribed 50 mg of sertraline each 12 hours daily and the second group is prescribed 50 mg four hours before coitus. 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: **IRCT20180401039167N1**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **prospective**

Last update: **2019-01-29, 1397/11/09**

Update count: **1**

##### Registration date

2018-06-10, 1397/03/20

##### 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

2018-06-22, 1397/04/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative Study of Therapeutic Effect of Two Medicinal Procedures of Sertraline in Premature Ejaculation

### Public title

Study of Therapeutic Effect of Sertraline 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 65 years

#### Exclusion criteria:

Norologic Disorder Psychologic Disorder Age Less than 20 and Over 65 Years Urinary and Genital Infection History of Pelvic Surgery

### Age

From **20 years** old to **65 years** old

### Gender

Male

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **120**

### 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 two 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 Aja University of Medical Sciences

### Street address

Emam Reza Hospital, Sarhang etemadzadeh ve, 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.1396.111

## 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 Sertraline

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

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Sertraline will receive 50 mg 4 hours before coitus from Abidebi-Tehran Pharmaceutical Company for 8 weeks.

#### Category

## 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**

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**Postal code**

IR.26.110791

**Phone**

+98 21 2274 6600

**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 St

**City**

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**Phone**

+98 21 8609 5072

**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

**Street address**

Emam Reza Hospital, Sarhang Etemadzadeh st,  
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reza.bijan1345@ajaums.ac.ir

## Person responsible for scientific inquiries

#### Contact

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Artesh University of Medical Sciences

**Full name of responsible person**

Bijan Rezakhaniha

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## Person responsible for updating data

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**Fax****Email**

## 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