Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

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

Protocol summary

Study aim

Comprative 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 an urologist and, if approved, have an early ejaculation according to the definition of DMS-4 enrollred 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 : Norologic Disorder؛ Psycologic 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
Comprative 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 Psycologic 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

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
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+98 21 2274 6600
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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
Street address
Aja University of Medical Sciences, Sarhang Etemadzadeh Ave, Fatemi St
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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

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Person responsible for updating data

reza.bijan1345@ajaums.ac.ir

Contact

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Bijan Rezakhaniha

Position
Associate professor

Latest degree
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Urology

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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