Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of two methods of sertraline therapy for the treatment of patients with premature ejaculation

Protocol summary

Summary

This in study comparative therapeutic effects of two medicinal procedures setraline4 hours before coitus and each 12 hours in patients' premature ejaculation refers to 501 hospital. Conditions, entry into the study were: mean age of 16 to 75 years with Intercourse at least once a week and premature ejaculation. Conditions, withdrawal from the study includes of erection dysfunction, urinary tract infections, neurological and systemic disorders, severe mental disorders, history of alcoholism, drug use or drug (Drug abuse) is considered. In this study, the total number of samples required prepared cards. Ejaculation latencies before treatment (mean time at least three times in the coitus) and the fourth week after treatment by the patient's wife with accurately measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101415006N1**
Registration date: **2014-10-15, 1393/07/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-15, 1393/07/23

Registrant information

Name
Vahid Najafi
Name of organization / entity
Army College of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 2348 2026
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Recruitment status

Recruitment complete

Funding source

Army College of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of sertraline therapy for the treatment of patients with premature ejaculation

Public title

Comparison of two methods of treatment of sertraline in the treatment of premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male patients; having sex at least once a week; no disease in the form of inclusion. Exclusion criteria: if the drug has side effects; lack of satisfaction to continue testing; couples apart during testing.

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Army 501 Hospital

Street address
Tehran - Etemadzadeh - 501 Army Hospital

City
tehran

Postal code

Approval date
2014-06-22, 1393/04/01

Ethics committee reference number
15006

Health conditions studied

1

Description of health condition studied
Patients with premature ejaculation

ICD-10 code
F52.4

ICD-10 code description
Premature ejaculation

Primary outcomes

1

Description
Premature Ejaculation

Timepoint
Before and after intervention

Method of measurement
Assessment of satisfaction spouses before and after intervention

Secondary outcomes

1

Description
Headache

Timepoint
During intervention

Method of measurement
Qualitatively, and through the person's statements

2

Description
Dizziness

Timepoint
During intervention

Method of measurement
Qualitatively, and through the person's statements

3

Description
Vomiting

Timepoint
During intervention

Method of measurement
Qualitatively, and through the person's statements. and after intervention

Intervention groups

1

Description
Treatment effects sertraline (20 mg) for 4 hours prior to sexual intercourse e in patients with early ejaculation For 12 months

Category
Treatment - Drugs

2

Description
Treatment effects sertraline (20 mg) for 12 hours prior to sexual intercourse e in patients with early ejaculation For 12 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
501 Army Hospital

Full name of responsible person
Vahid Najafi

Street address
Army 501 Hospital- Etemadzadeh -Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Medical Sciences Iranian Army
Full name of responsible person
Dr. Kamran Azma
Street address
Army 501 Hospital, Western Fatemi, Etemadzadeh, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Medical Sciences Iranian Army
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Army University of Medical Sciences
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Vahih Najafi
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty