Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of tadalafil and serteraline cobmination therapy with serteraline and placebo in treatment of premature ejaculation

Protocol summary

Summary

Premature ejaculation is the most common male sexual dysfunction in worldwide. In recent years SSRIs have been used successfully in the treatment of premature ejaculation and PDE-5I that are also the preferred treatment for erectile dysfunction have been used alone or in combination with an SSRI for the treatment of premature ejaculation by several researchers. This double-blind randomized clinical trial plans to compared the effect of the combination therapy with sertraline and tadalafil on patients with primary premature ejaculation with the combination therapy with sertraline and placebo. All men aged between 18 and 50 years with complaints of premature ejaculation who referred to Razi Hospital and three private clinics in the Gilan Province are divided into two groups. Group A are treated with sertraline 50mg and tadalafil 10mg before intercourse for 6 weeks and group B are treated with sertraline 50mg and placebo before intercourse for 6 weeks. At the end of the study, the mean Intravaginal Ejaculatory Latency Time (IELT) during the last three weeks will be calculated and will be compared with baseline IELT. Also, before and after study Premature Ejaculation Profile questionnaire (PEP) will be completed by the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811101853N7**
Registration date: **2012-09-15, 1391/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-15, 1391/06/25

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2012-04-29, 1391/02/10

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of tadalafil and serteraline cobmination therapy with serteraline and placebo in treatment of premature ejaculation

Public title

The effects of tadalafil and serteraline cobmination therapy in treatment of premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: People who have been married at least for 6 months; Patients who suffer from primary premature ejaculation (PE); Age between 50-18 years
Exclusion criteria: A history of mental illness and physical illness such as liver disease and diabetes Mellitus (DM); Previous surgery on sexual function was affected; Currently abusing alcohol or drug; Patients with secondary PE associated with erectile dysfunction (ED); Contraindications of taking PDEIs

Age
From **18 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University of Medical Science
Street address
Namjoo Street
City
Rasht
Postal code
41448-95655
Approval date
2012-04-26, 1391/02/07
Ethics committee reference number
1910051506

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
The time from penetration to ejaculation
Timepoint
before and the end of the study
Method of measurement
timer

Secondary outcomes

1

Description
Control over ejaculation
Timepoint
before and the end of the study
Method of measurement
PEP questionnaire

2

Description
Satisfaction
Timepoint
before and the end of the study
Method of measurement
PEP questionnaire

3

Description
Distress
Timepoint
before and the end of the study
Method of measurement
PEP questionnaire

4

Description
problem with partner
Timepoint
before and the end of the study
Method of measurement
PEP questionnaire

Intervention groups

1

Description
Sertraline 50 mg daily with tadalafil 10 mg before intercourse
Category
Treatment - Drugs

2

Description
Sertraline 50 mg daily with placebo before intercourse
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Dr. Reza Shahrokhi (Rezident)
Street address
Razi Hospital
City
Rasht

2

Recruitment center
Name of recruitment center
Dr. Gholamreza Mokhtari's clinic
Full name of responsible person
Dr. Gholamreza Mokhtari
Street address
Navab Ave., Golsar Sq., Rasht
City
Rasht

3

Recruitment center
Name of recruitment center
Dr. Iradj Khosropanah's clinic
Full name of responsible person
Dr. Iradj Khosropanah
Street address
Golsar Sq., Rasht
City
Rasht

4

Recruitment center
Name of recruitment center
Dr. Ali Roshani's clinic
Full name of responsible person
Dr. Ali Roshani
Street address
Motahari Ave., Anzali
City
Anzali

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Center
Full name of responsible person
Dr. Siavash Falahatkar
Street address
Razi Hospital, Urology Research Center
City
Rasht
Grant name
10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Center
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
Urology Research Center
Full name of responsible person
Dr. Reza Shahrokhi
Position
Co worker/Resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Urology Research Center
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Dr. Gholamreza Mokhtari
Position
Associated Professor of Guilan University of Medical

Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Samaneh Esmaeili

Position

Master/ Researcher of Urology Research Center

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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