Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparative study on the efficacy of add-on sertraline or dapoxetine to PDE-5 inhibitors (phosphodiesterase type 5) on the erectile function and intra-vaginal ejaculation latency time (IELT) among patients with concomitant erectile dysfunction and premature ejaculation

Protocol summary

Study aim
Determining the effectiveness of adding sertraline and dapoxetine (phosphodiesterase inhibitors type 5) on erectile function and latent and intravaginal ejaculation time in patients with concomitant erectile dysfunction and premature ejaculation

Design
Clinical trial with control group, with parallel groups, one-way blind, randomized, phase-3 on 50 patients. SPSS software was used for randomization.

Settings and conduct
This double-blind clinical trial study was performed in 1400 in psychiatric therapists of Khorshid Hospital in Isfahan. In this study, the patient and the person examining the outcome of the treatment will be unaware of the type of medication received by patients.

Participants/Inclusion and exclusion criteria
In this study, patients with erectile dysfunction and premature ejaculation are included in the study. Patients with genitourinary tract infection, neurological disorders and underlying diseases, and people with Selective Serotonin Reuptake Inhibitors (SSRI) allergies or a history of pelvic surgery will not be included in the study.

Intervention groups
50 patients with sexual dysfunction are distributed in two groups of 25 people. The first group will receive 60 mg of dapoxetine one to three hours before sexual activity, and the second group will receive 50 mg of sertraline twice daily for one month. This will continue for 3 months. Then, the duration of intravaginal ejaculation in all individuals (average time in at least three sexual intercourses), at the beginning of the study and also in weeks 4, 8 and 12 after starting the drug by the spouse from the time of vaginal penetration to the time of ejaculation with a stopwatch will be measured.

Main outcome variables
Erectile function, Premature ejaculation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150913024006N5**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date
2021-03-02, 1399/12/12

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-03, 1400/01/14

Expected recruitment end date
2022-03-18, 1400/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the efficacy of add-on sertraline or dapoxetine to PDE-5 inhibitors (phosphodiesterase type 5) on the erectile function and intra-vaginal ejaculation latency time (IELT) among patients with concomitant erectile dysfunction and premature ejaculation

Public title

The effect of adding sertraline to dapoxetine in relieving sexual problems in men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Erectile dysfunction anda score above 20 in the International index of Erectile Function Treatment with phosphodiesterase 5 inhibitors (such as Sildenafil, Tadalafil) more than three months before the start of the study Living in a stable and heterosexual relationship and intention for maintaining the relationship until the end of the study period Possibility of sexual intercourse at least once a week

Exclusion criteria:

Ŝensitivity to Selective Serotonin Reuptake Inhibitors(SSRI) drugs Urinary tract infections Neurological disorders History of pelvic surgery Underlying diseases such as diabetes, heart disease, hypertension, thyroid disorder Use of psychiatric drugs Alcohol consumption

Age

From **18 months** old to **80 months** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization patients in the two groups simple randomization is used. For this purpose, 50 pieces of paper with the letter A written on 25 of them and the letter B written on the other 25 pieces are poured into the box. Each patient is asked to take a sheet out of the box when entering the study. Depending on what is written on the sheet, the patient enters the first group (A) or the second group (B).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed by two-blind method. Medications in similar packages prepared by the pharmaceutical company are provided by the researcher to patients who are unaware of the contents of the packages. The outcome of treatment is also assessed by another psychiatrist who is unaware of the type of medication the patient is receiving.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Research faculty, Isfahan University of Medical Sceices, Hezarjerib street

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Province

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Postal code

8434193474

Approval date

2020-05-19, 1399/02/30

Ethics committee reference number

IR.MUI.MED.REC.1399.766

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes

1

Description

Erectile function

Timepoint

Before the intervention and 4, 8, 12 weeks after the start of the intervention

Method of measurement

Erectile Performance Index Questionnaire

2

Description
Premature ejaculation
Timepoint
Before the intervention and 4, 8, 12 weeks after the start of the intervention
Method of measurement
The interval between the beginning of sexual intercourse and the time of ejaculation in minutes in the before the intervention and 4, 8, 12 weeks after the start of the intervention

Secondary outcomes

1

Description
Premature ejaculation
Timepoint
Before the intervention and 4, 8, 12 weeks after the start of the intervention
Method of measurement
The interval between the beginning of sexual intercourse and the time of ejaculation in minutes

Intervention groups

1

Description
Intervention group 1: This group of patients take a 60 mg oral tablet of dapoxetine made by Exir Pharmaceutical Company one to three hours before the start of sexual activity with the maximum allowed dose for 24 hours.
Category
Treatment - Drugs

2

Description
Intervention group 2: This group takes a 50 mg Sertraline tablet made by Osweh Pharmaceutical Company twice a day for a month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry clinic, Noor hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Esfahan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The plan belongs to a government agency and cannot be shared.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available