

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of Tamarind seed extract product (*Tamarindus indica* L.) with Sertraline in treatment of premature ejaculation

Protocol summary

Study aim

Comparison of the effects of Tamarind seed extract product (*Tamarindus indica* L.) with Sertraline in treatment of premature ejaculation

Design

This study is a randomized clinical trial study without a placebo group and a comparison in terms of the therapeutic effects of tamarind and sertraline on the treatment of premature ejaculation. 40 people (twenty people in each group) will be examined in this study from May 1403 to June 1403.

Settings and conduct

This study is a randomized clinical trial study without a placebo group and a comparison in terms of the therapeutic effects of tamarind and sertraline on the treatment of premature ejaculation. 40 people (twenty people in each group) will be examined in this study from May 1403 to June 1403.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1- Being monogamous and married for at least 6 months ago 2- age between 50-20 years old 3- A score greater than 8 in the PEDT questionnaire 4- Written and informed consent to participate in the study
Exclusion Criteria: 1- Unwillingness to continue studying 2- The occurrence of severe side effects that cause severe concern for the patient, or are dangerous for the patient's health as determined by the doctor 3- Failure to execute orders accurately and completely 4- Using treatments outside the study protocol 5- Not being able to accurately measure IELT 6- Chronic and long-term use of any kind of psychoactive drug or any type of narcotic drug 7- ulcerative colitis; Chronic constipation, digestive discomfort, kidney cleansing, high blood pressure

Intervention groups

Intervention group patients: oral intervention product, one capsule once a day for one month
Standard treatment group patients: Sertraline 50 mg once a day for one month

Main outcome variables

Duration of ejaculation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140926019295N4**

Registration date: **2024-04-09, 1403/01/21**

Registration timing: **prospective**

Last update: **2024-04-09, 1403/01/21**

Update count: **0**

Registration date

2024-04-09, 1403/01/21

Registrant information

Name

Ali Sahraian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 9319

Email address

sahraian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-06-22, 1403/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Tamarind seed extract product (*Tamarindus indica* L.) with Sertraline in treatment of premature ejaculation

Public title

Evaluation of the effects of Tamarind seed extract product (*Tamarindus indica* L.) with Sertraline in treatment of premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being monogamous and married for at least 6 months ago age between 50-20 years old PEDT questionnaire score greater than 8 Written and informed consent to participate in the study

Exclusion criteria:

Use of treatments outside the study protocol ulcerative colitis; Chronic constipation, digestive discomfort, kidney cleansing, high blood pressure Not being able to accurately measure the IELT score Chronic and permanent use of any type of psychoactive drug or any type of narcotic drug

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple randomization. The randomization unit is individual and the patient randomization tool is a table of random numbers using with computer. The starting point was completely random (choosing a number on the table with eyes closed) and choosing the direction of movement in the table in the downward direction. Patients are randomly placed in one of the study groups with the help of a random number table and receive the relevant intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome evaluator and the statistical analyst of the results will be blinded. The capsules of the drug and the standard drug have the same shape, and after being filled, they are packed in packages of 30 pieces that are completely similar in terms of shape. Only the researcher can decipher the contents of each capsule package based on the initial form stored of the randomization

results. The person responsible for delivering the medicine, the patient, the doctor, the person responsible for evaluating the results will not know about the coding. The results of group therapy and intervention will be delivered to the statistical analyst under the titles of groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Karim Khan Zand St. Faculty of Medicine

City

Shiraz

Province

Fars

Postal code

7144714189

Approval date

2024-03-02, 1402/12/12

Ethics committee reference number

IR.SUMS.MED.REC.1402.542

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 weeks after the start of Drug

Method of measurement

Measure the time in seconds by the stopwatch by the patient's wife

Secondary outcomes

empty

Intervention groups

1

Description

Tamarind seed capsule is standardized to contain at least 80 mg of active ingredient, it will be consumed once a day for one month, this drug is made by Dayan Teb Elixir Company.

Category

Treatment - Drugs

2

Description

Sertraline 50 mg will be taken once a day for one month, manufactured by Octorco pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebnsina Hospital

Full name of responsible person

Payam Sadeghi

Street address

Hafezie avenue

City

Shiraz

Province

Fars

Postal code

7144676541

Phone

+98 71 3228 9604

Email

payamsadeghi68@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempour

Street address

Shiraz, Zand St., Shiraz University of Medical Sciences
Central Building

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

50

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

Shiraz University of Medical Sciences

Full name of responsible person

Payam Sadeghi

Position

Psychiatry Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Chamran Blv. Hafez hospital- psychiatry department

City

Shiraz

Province

Fars

Postal code

7144734189

Phone

+98 71 3647 9531

Email

payamsadeghi68@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ali Sahraian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Department of Psychiatry, Hafez Hospital ,Shiraz
University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7144734189

Phone

+98 71 3647 9531

Email

sahraian@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Payam Sadeghi

Position

Psychiary Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Chamran Blv. Hafez hospital- psychiatry department

City

Shiraz

Province

Fars

Postal code

۳۴۷۸۶-۷۱۹۴۶

Phone

+98 71 3647 9319

Email

payamsadeghi68@gmail.com

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

No - There is not 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