# 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)

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+98 71 3627 9319

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**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
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**Postal code**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Hashem Hashempour
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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 Rezident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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**Position**
Professor
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Subspecialist

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## Person responsible for updating data

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## 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