Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy and safety of Tramadol, Paroxetine and placebo in patients with life long premature ejaculation

Protocol summary

Summary

In this double-blind, placebo-controlled, randomized clinical trial, the effects of tramadol, paroxetine and placebo in the treatment of premature ejaculation will be investigated. All of the participants would be enrolled in the study after medical and sexual examination and rejecting erectile dysfunction. Eligible patients would be divided into 3 groups, randomly. A group will be treated with tramadol 50 mg, another group will be treated with paroxetine 30 mg and third group will receive placebo. The medications will used on demand (3-4 hours before intercourse). Before beginning treatment, patients should be asked to measure their mean Intravaginal ejaculation latency time (IELT), at least the 3 last intercourses in a row by using a stopwatch. At the end of 12 weeks, the mean measured Intravaginal ejaculation latency time (IELT) by the patient in the last 3 weeks (including at least 3 intercourses) will be calculated. The PEP (Premature Ejaculation Profile) inventory will be completed separately for each patient at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008304582N2**
Registration date: **2014-10-04, 1393/07/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-04, 1393/07/12

Registrant information

Name

Ali Hamidi Madani

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 13 1552 5259

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Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of Tramadol, Paroxetine and placebo in patients with life long premature ejaculation

Public title

Comparison of efficacy and safety of Tramadol, Paroxetine and placebo in treatment of life long premature ejaculation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least one year of their marriage is past; to be between 18-50 years of age; have the possibility of intercourse at least once a week, ability to

read and write Exclusion criteria: People who have a history of mental diseases, a physical illness such as diabetes and liver disease, alcohol or drug abuse, a history of surgery that has been effective on sexual function; history of endocrine disease, prostatitis; history of paroxetine and tramadol during the last 3 months

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

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

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 Sciences

Street address
Gas Square, Vice-Chancellor for Research of Guilan University of Medical Sciences

City
Rasht

Postal code

Approval date
2014-08-19, 1393/05/28

Ethics committee reference number
1930231601

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
Intravaginal ejaculation latency time (IELT)

Timepoint
Baseline and 3 months after treatment

Method of measurement
Ask the patient based on the PEP Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Tramadol 50 mg, 3 to 4 hours before the intervention (on demand) for 12 weeks

Category
Treatment - Drugs

2

Description
Paroxetine 20 mg, 3 to 4 hours before the intervention (on demand) for 12 weeks

Category
Treatment - Drugs

3

Description
Placebo, 3 to 4 hours before the intervention (on demand) for 12 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Urology Clinic of Razi Hospital

Full name of responsible person
Dr. Reza Motiee

Street address
Clinic of Urology, Razi Hospital, Sardar Jangal Street

City
Rasht

2

Recruitment center

Name of recruitment center
Dr. Ali Hamidi Madani's Clinic

Full name of responsible person
Dr. Ali Hamidi Madani

Street address
Dr. Ali Hamidi Madani's Clinic, Hafez Street
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Centre
Full name of responsible person
Dr. Siavash Falahatkar
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Urology Research Centre, Razi Hospital, Sardar Jangal Street
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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 Centre
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

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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