

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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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

Web page address<http://www.gums.ac.ir/urc/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Urology Research Centre

Full name of responsible person

Dr. Siavash Falahatkar

Street address

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****Contact****Name of organization / entity**

Urology Research Center

Full name of responsible person

Dr. Reza Motiei

Position

Co worker/Resident

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Urologist / Associate Professor of Guilan University of Medical Sciences

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Urology Research Center

Full name of responsible person

Samaneh Esmaeili

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Researcher of Urology Research Center/ Master

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Web page address<http://www.gums.ac.ir/urc/>**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